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(71) Applicant *(for all designated States except US)*: **ENDIUS, INC.** [US/US]; 23 West Bacon Street, Plainville, Massachusetts 92762 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **DIPOTO, Gene** [US/US]; 23 Crockett Road, Upton, Massachusetts 01568 (US). **SHLUZAS, Alan** [US/US]; 84 Acorn Street, Millis, Massachusetts 02054 (US). **ROSSIN, Victor** [US/US]; 2 Kelly Road, Cambridge, Massachusetts 02139 (US). **ANDERSON, Stephen** [US/US]; 52 Sweetgrass Lane, Holliston, Massachusetts 01746 (US). **BAKER, Daniel** [US/US]; 13203 39th Ave. NE, #101, Seattle, Washington 98125-4615 (US).

(74) Agent: **DELANEY, Karoline, A.?**; 2040 Main Street, Fourteenth Floor, Irvine, California 92614 (US).

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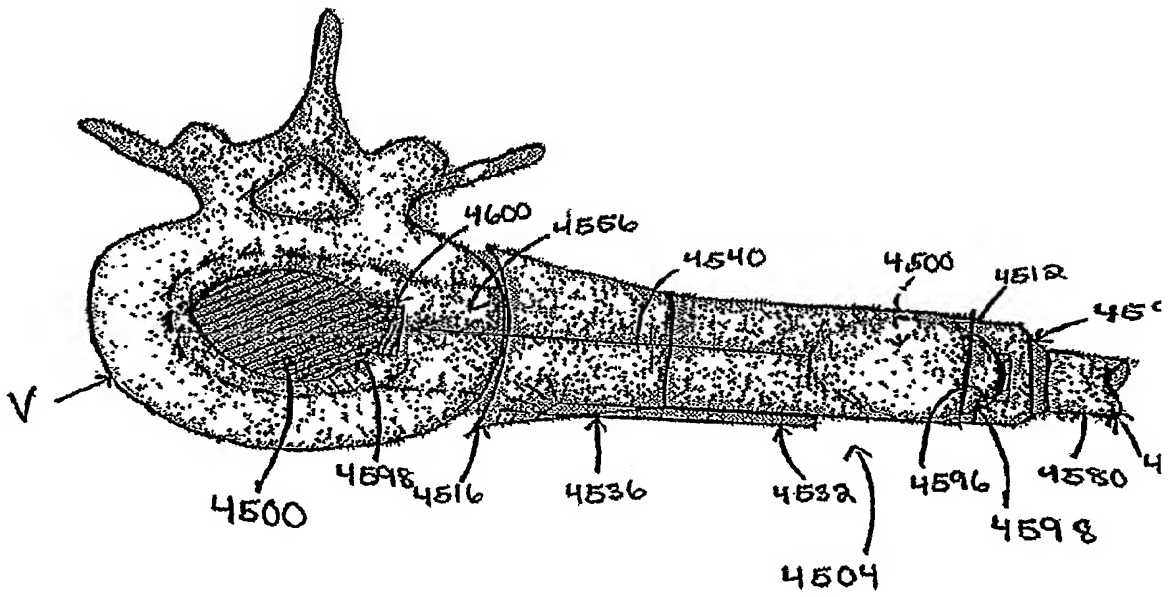
(54) Title: METHODS, SYSTEMS AND APPARATUSES FOR PERFORMING MINIMALLY INVASIVE SPINAL PROCEDURES



(57) Abstract: In one embodiment, a surgical access device 5304a comprising a passage and a distal portion 5324 may be used to perform a surgical procedure. The access device 5304a may be actuatable between a first configuration wherein the passage has a first cross-sectional area at the distal portion 5324 suitable for insertion into the patient and a second configuration wherein the passage has an enlarged cross-sectional area at said distal portion 5324. The access device 5304a may further be capable of providing access to a surgical location A. The passage is preferably capable of having an instrument 5376 or implant 5378 inserted therethrough to the surgical location A.

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METHODS, SYSTEMS AND APPARATUSES FOR PERFORMING MINIMALLY INVASIVE SPINAL PROCEDURES

Background of the Invention

Field of the Invention

[0001] This application relates to minimally invasive surgical procedures, and more particularly to replacing an intervertebral disc of a patient with a prosthetic device.

Description of the Related Art

[0002] Chronic back pain can have any of a number of causes or a combination of causes. For example, acute damage to and / or progressive degeneration of a disc, which is located in the interbody space defined between adjacent vertebrae, can lead to pain as the load-bearing and flexibility providing functions of the disc are no longer effectively performed. A number of treatments have been proposed for this condition. Fusion is a procedure whereby a graft intended to promote bone growth within the interbody space replaces some or all of the material in the interbody space. The bone growth causes the adjacent vertebrae to be joined together, after which the two vertebrae essentially become one and flexibility is eliminated. While this approach can reduce the pain associated with disc conditions, the substantial reduction or complete elimination of flexibility at the problem disc can lead to greater stress on adjacent discs and other spine problems.

[0003] Traditionally, these and other spine treatments have been performed by way of open surgery. In open surgery, the surgeon typically makes one ore more large incisions and cuts and / or strips muscle tissue surrounding the spine in order to access the vertebrae. Because the amount of tissue exposed is so great, care must be taken not to injure nerve tissue in the area. Consequently, these traditional surgical procedures carry high risks of scarring, pain, significant blood loss, and extended recovery times.

[0004] Apparatuses for performing minimally invasive techniques have been proposed to reduce the trauma of spine surgery by reducing the size of the incision and the degree of muscle stripping in order to access the vertebrae. One such apparatus provides a constant diameter cannula which is made narrow in order to provide a small entry profile. As a result, the cannula provides minimal space for the physician to observe the body structures and manipulate surgical instruments in order to perform the required procedures. A narrow cannula is typically too small to perform most spine procedures. Accordingly, several cannula are required to perform even the simplest procedure.

Summary of the Invention

[0005] Accordingly there is a need in the art for minimally invasive apparatuses, systems and methods for treating intervetebral disc and other spinal failures in a manner that reduces patient trauma. In some embodiments, these apparatuses, systems and methods may restore much of the biomechanical functionality of a healthy spine. In other embodiments, they may stabilize the spine in a more rigid, but also more supported position.

[0006] In one embodiment, a surgical access device comprising a passage and a distal portion may be provided. The access device is further actuatable between a first configuration wherein the passage has a first cross-sectional area at the distal portion suitable for insertion into the patient and a second configuration wherein the passage has an enlarged cross-sectional area at said distal portion. The access device is capable of providing access to an interbody space, and the passage is capable of having a prosthetic spinal disc implant inserted therethrough to the interbody space.

[0007] In another embodiment, a surgical access device comprising a passage and a distal portion may be provided. The access device is further actuatable between a first configuration wherein the passage has a first cross-sectional area at the distal portion suitable for insertion into the patient and a second configuration wherein the passage has an enlarged cross-sectional area at said distal portion. The access device is capable of providing access to an interbody space, and the passage is capable of having a replacement disc nucleus inserted therethrough to the interbody space.

[0008] In yet another embodiment, a system for stabilizing at least two adjacent vertebrae of the spine of a patient may be provided. The system comprises an access device having a passage and a distal portion, and a motion preserving, stabilization device. The access device is actuatable between a first configuration wherein the passage has a first cross-sectional area at the distal portion suitable for insertion into the patient and a second configuration wherein the passage has an enlarged cross-sectional area at said distal portion. The access device is also capable of providing access to at least one of the two adjacent vertebrae. The motion preserving, stabilization device is configured for insertion through the passage and attachment between the at least two adjacent vertebrae.

[0009] In another embodiment, a system for fixing at least two adjacent vertebrae of the spine of a patient is provided. The system comprises an access device having a passage and a distal portion, and a first fastener for transfacet fixation. The access device is actuatable between a first configuration wherein the passage has a first cross-sectional area at the distal portion suitable for insertion into the patient and a second configuration wherein the passage has an enlarged cross-sectional area at said distal portion. The access device is capable of providing access to at least one of the two adjacent vertebrae. The first fastener is configured for insertion through the passage.

[0010] In another embodiment, an access device is inserted through an incision in skin of a patient. The access device is expanded from a first configuration to a second configuration, the second configuration having an enlarged cross-sectional area at a distal portion of said access device such that the distal portion extends across at least a portion of the interbody space. A prosthetic spinal disc implant is then delivered through the access device.

[0011] In another embodiment, a portion of a disc of a patient is replaced. The disc has an annulus and a nucleus. An access device is inserted through an incision in the skin of the patient generally postero-laterally. The access device is advanced until a distal portion thereof is located adjacent the spine.

The access device is inserted in a first configuration that has a first cross-sectional area at the distal portion thereof. The access device is configured such that the distal portion thereof is enlarged from the first configuration to a second configuration. In the second configuration, the distal portion extends across at least a portion of the disc. An implement is advanced through the access device to the intervertebral space. An aperture is formed in the annulus. A disc evacuation tool is advanced through the access device and through the aperture. At least a portion of the nucleus is removed through the access device to at least partially evacuate the intervertebral space. A replacement disc nucleus is delivered into the partially evacuated intervertebral space through the access device.

[0012] In another embodiment, the spine of a patient is treated. An access device is inserted through a minimally invasive incision in the skin of the patient. The access device is advanced until a distal portion thereof is located adjacent the spine. The access device is expanded from a first configuration to a second configuration. The second configuration of the access device has an enlarged cross-sectional area at the distal portion thereof such that the distal portion extends across at least a portion of a disc. A replacement disc nucleus is delivered into the intervertebral space through the access device.

[0013] In another embodiment, a device is used to provide access to a surgical location within a patient. The device has an elongate body having a proximal end, a distal end, and a passage extending therebetween. The elongate body defines a length between the proximal and distal ends, such that the proximal end can be positioned outside the patient and the distal end can be positioned inside the patient adjacent the surgical location. The distal end is shaped to the contours of the surgical location. The elongate body is actuatable between a first configuration sized for insertion into the patient and a second configuration, wherein the cross-sectional area of said passage at a first location is greater than the cross-sectional area of said passage at a second location, wherein the first location is distal to the second location.

[0014] In another embodiment, a device provides access to a surgical location within a patient. The device includes an elongate body that has a proximal end, a distal end, and a passage extending therebetween. The elongate body defines a length between the proximal and distal ends such that the proximal end can be positioned outside the patient and the distal end can be positioned inside the patient adjacent the surgical location. The distal end is shaped to substantially conform to a contour of an anatomical structure near the surgical location. The elongate body is actuatable between a first configuration sized for insertion into the patient and a second configuration wherein the cross-sectional area of the passage at a first location is greater than the cross-sectional area of the passage at a second location, wherein the first location is distal to the second location.

[0015] In another embodiment, a device for accessing an intervertebral disc of a patient having a nucleus and an annulus has an elongate body. The elongate body has a proximal end, a distal end, and a passage extending therebetween. The elongate body defines a length between the proximal and distal ends such that the proximal end can be positioned outside the patient and the distal end can be advanced

inside the patient and into the annulus. The elongate body is actuatable between a first configuration sized for advancement into the annulus and a second configuration wherein the cross-sectional area of the passage at a first location is greater than the cross-sectional area of the passage at a second location, wherein the first location is distal to the second location.

[0016] In another embodiment, a device for accessing an intervertebral disc of a patient having a nucleus and an annulus is provided. The device includes an elongate body and a viewing element. The elongate body has a proximal end, a distal end, a passage extending therebetween, and a viewing element aperture. The viewing element aperture is located near the distal end. The elongate body defines a length between the proximal and distal ends such that when the distal end is advanced into the patient to the annulus, the proximal end is positioned outside the patient. The viewing element extends through the aperture into the passage.

[0017] In another embodiment, at least two adjacent vertebrae of the spine a patient are stabilized. An access device is inserted through an incision in the skin of the patient generally posteriorly. The access device is advanced until a distal portion thereof is located adjacent the spine. The access device is inserted in a first configuration that has a first cross-sectional area at the distal portion thereof. The access device is configured such that the distal portion thereof is enlarged from the first configuration to a second configuration wherein the distal portion is large enough to extend across at least a portion of the adjacent vertebrae. A bone probe is advanced through the access device to one of the two adjacent vertebrae. A hole is formed in one of the two adjacent vertebrae. A tap is advanced through the access device to one of the two adjacent vertebrae. The tap is advanced into at least a portion of the hole to create a tapped hole portion. A fastener is delivered through the access device to the hole. A connecting element that is delivered through the access device. The dynamic connecting element is coupled to the fastener in a manner that permits motion between the adjacent vertebrae.

[0018] In another embodiment, two adjacent vertebrae in a spine of a patient are treated. An access device is inserted through a minimally invasive incision in the skin of the patient. The access device is advanced until a distal portion thereof is located adjacent the spine. The access device is expanded from a first configuration to a second configuration. The second configuration has an enlarged cross-sectional area at the distal portion thereof such that the distal portion extends across at least a portion of the two adjacent vertebrae. A motion preserving, stabilization device is delivered to a location between the two adjacent vertebrae through the access device.

[0019] In another embodiment, a method of treating a spine of a patient is provided. An access device is inserted through a minimally invasive incision in the skin of the patient. The access device is advanced until a distal portion thereof is located adjacent the spine. The access device is expanded from a first configuration to a second configuration. The second configuration has an enlarged cross-sectional area at the distal portion thereof such that the distal portion extends across at least one of two adjacent vertebrae.

A stabilization device is delivered through the access device to a location between the two adjacent vertebrae. The stabilization device is configured to preserve motion between the two adjacent vertebrae.

[0020] In another embodiment, a system is provided that is configured to apply a dynamic stabilization device between two adjacent vertebrae. The system includes an access device, a bone probe, and a tap. The access device has a first configuration and a second configuration. The first configuration has a first cross-sectional area at the distal portion thereof for insertion. In the second configuration, the distal portion is enlarged to extend across at least one of the two adjacent vertebrae. The access device is configured to permit the dynamic stabilization device to be advanced therethrough. The bone probe is configured to be advanced through the access device to form a hole in one of the two adjacent vertebrae. The tap is configured to be advanced through the access device to thread the hole to create a tapped hole.

[0021] Another embodiment provides for a method to fix adjoining vertebrae of the spine of a patient. An access device is inserted into the patient at a surgical location adjacent the spine. This access device is inserted in a first configuration with a first cross-sectional area defined by its distal portion. Once at or near the surgical location, the access device is actuated to a second configuration having an enlarged cross-sectional area at its distal portion. With the access device in place, a fastener is delivered through the access device to the surgical location. The fastener is then advanced through a first vertebra and into a second vertebra. This fixation technique allows for the fixation of two adjacent vertebrae with minimal disruption and trauma to the surrounding tissue.

Brief Description of the Drawings

[0022] Further objects, features and advantages of the invention will become apparent from the following detailed description taken in conjunction with the accompanying figures showing illustrative embodiments of the invention, in which:

[0023] **FIGURE 1** is a perspective view of one embodiment of a surgical system and one application for treating the spine of a patient.

[0024] **FIGURE 2** is a perspective view of one embodiment of an access device in a reduced profile configuration.

[0025] **FIGURE 3** is a perspective view of the access device of **FIGURE 2** in a first enlarged configuration.

[0026] **FIGURE 4** is a perspective view of the access device of **FIGURE 2** in a second enlarged configuration.

[0027] **FIGURE 5** is a view of one embodiment of a skirt portion of an access device.

[0028] **FIGURE 6** is a view of another embodiment of a skirt portion of an access device.

[0029] **FIGURE 7** is a perspective view of another embodiment of an access device.

[0030] **FIGURE 8** is a side view of the access device of **FIGURE 7**.

[0031] **FIGURE 9** is a front view of the access device of **FIGURE 7**.

[0032] **FIGURE 10** is a bottom view of the access device of **FIGURE 7**.

[0033] **FIGURE 11** is a perspective view of the access device of **FIGURE 7** in a first configuration.

[0034] **FIGURE 12** is an exploded perspective view of the access device of **FIGURE 7** in a second configuration.

[0035] **FIGURE 13** is a sectional view illustrating one stage of one application for treating the spine of a patient.

[0036] **FIGURE 14** is a side view of one embodiment of an expander apparatus in a reduced profile configuration.

[0037] **FIGURE 15** is a side view of the expander apparatus of **FIGURE 14** in an expanded configuration.

[0038] **FIGURE 16** is a sectional view of the expander apparatus of **FIGURES 14-15** inserted into the access device of **FIGURE 2**, which has been inserted into a patient.

[0039] **FIGURE 17** is a sectional view of the expander apparatus of **FIGURES 14-15** inserted into the access device of **FIGURE 2** and expanded to the expanded configuration to retract tissue.

[0040] **FIGURE 18** is an exploded perspective view of one embodiment of an endoscope mount platform.

[0041] **FIGURE 19** is a top view of the endoscope mount platform of **FIGURE 18** coupled with one embodiment of an indexing arm and one embodiment of an endoscope.

[0042] **FIGURE 20** is a side view of the endoscope mount platform of **FIGURE 18** illustrated with one embodiment of an indexing arm and one embodiment of an endoscope.

[0043] **FIGURE 21** is a perspective view of one embodiment of an indexing collar of the endoscope mount platform **FIGURE 18**.

[0044] **FIGURE 22** is a perspective view of one embodiment of an endoscope.

[0045] **FIGURE 23A** is a top perspective view of one embodiment of an access system.

[0046] **FIGURE 23B** is a side perspective view of the access system of **FIGURE 23A**.

[0047] **FIGURE 23C** is a top view of the access system of **FIGURE 23A**.

[0048] **FIGURE 24A** is a perspective view of one embodiment of a lighting element.

[0049] **FIGURE 24B** is a perspective view of another embodiment of a lighting element.

[0050] **FIGURE 24C** is a perspective view of another embodiment of a lighting element.

[0051] **FIGURE 25** is a partial sectional view of one stage of one application of a method for treating the spine of a patient.

[0052] **FIGURE 26** is a perspective view of one embodiment of a fastener.

[0053] **FIGURE 27** is an exploded perspective view of the fastener of **FIGURE 26**.

[0054] **FIGURE 27A** is an enlarged side view of one embodiment of a biasing member illustrated in **FIGURE 27** taken from the perspective of the arrow 27A.

[0055] **FIGURE 28** is a perspective view of one embodiment of a surgical instrument.

[0056] **FIGURE 29** is an enlarged sectional view of the fastener of **FIGURES 26-27** coupled with the surgical instrument of **FIGURE 28**, illustrating one stage of one application for treating the spine of a patient.

[0057] **FIGURE 30** is side view of one embodiment of another surgical instrument.

[0058] **FIGURE 31** is a partial sectional view of one stage of one application for treating the spine of a patient.

[0059] **FIGURE 32** is a side view of one embodiment of another surgical instrument.

[0060] **FIGURE 33** is a perspective view similar to **FIGURE 31** illustrating the apparatuses of **FIGURES 26** and **32**, in one stage of one application for treating the spine of a patient.

[0061] **FIGURE 34** is an enlarged sectional view of the apparatus of **FIGURES 26** and **32**, illustrating one stage of one application for treating the spine of a patient.

[0062] **FIGURE 35** is an enlarged sectional similar to **FIGURE 34**, illustrating one stage of one application for treating the spine of a patient.

[0063] **FIGURE 36** is an enlarged view in partial section illustrating one stage of one application for treating the spine of a patient.

[0064] **FIGURE 37** is a partial view of illustrating one stage of one application for treating the spine of a patient.

[0065] **FIGURE 38** is a perspective view of a spinal implant or fusion device constructed according to another embodiment showing a first side surface of the spinal implant.

[0066] **FIGURE 39** is a perspective view of the spinal implant of **FIGURE 38** showing a second side surface of the spinal implant.

[0067] **FIGURE 40** is a plan view of the spinal implant of **FIGURE 38** showing an upper surface of the spinal implant.

[0068] **FIGURE 41** is a side view of the spinal implant of **FIGURE 38** showing the first side surface.

[0069] **FIGURE 42** is a cross-sectional view of the spinal implant taken along the line 42-42 in **FIGURE 41**.

[0070] **FIGURE 43** is a perspective view of another embodiment of a spinal implant constructed according to another embodiment showing a first side surface of the spinal implant.

[0071] **FIGURE 44** is a perspective view of the spinal implant of **FIGURE 43** showing a second side surface of the spinal implant.

[0072] **FIGURE 45** is a plan view of the spinal implant of **FIGURE 43** showing an upper surface of the spinal implant.

[0073] **FIGURE 46** is a side view of the spinal implant of **FIGURE 43** showing the first side surface.

[0074] **FIGURE 47** is a cross-sectional view of the spinal implant taken along the line 47-47 in **FIGURE 46**.

[0075] **FIGURE 48** is a view showing a pair of the spinal implants of **FIGURE 38** in first relative positions between adjacent vertebrae.

[0076] **FIGURE 49** is a view showing a pair of the spinal implants of **FIGURE 38** in second relative positions between adjacent vertebrae.

[0077] **FIGURE 50** is a view showing the spinal implant of **FIGURE 43** between adjacent vertebrae.

[0078] **FIGURE 51** is a view showing a spinal implant being inserted between the adjacent vertebrae according to one application.

[0079] **FIGURE 52** is a side view of an apparatus according to another embodiment.

[0080] **FIGURE 53** is a front view of the apparatus of **FIGURE 52**.

[0081] **FIGURE 54** is a top view of the apparatus of **FIGURE 52**.

[0082] **FIGURE 55** is a back view of the apparatus of **FIGURE 52**.

[0083] **FIGURE 56** is a bottom view of the apparatus of **FIGURE 52**.

[0084] **FIGURE 57** is a sectional view of the apparatus of **FIGURE 52**, used in conjunction with additional structure in a patient.

[0085] **FIGURE 58** is a longitudinal sectional view of the apparatus of **FIGURE 57** taken from line 58-58 of **FIGURE 57**.

[0086] **FIGURE 59** is a transverse sectional view of the apparatus of **FIGURE 58** taken from line 59-59 of **FIGURE 58**.

[0087] **FIGURE 60** is a sectional view, similar to **FIGURE 57**, illustrating an alternative position of the apparatus of **FIGURE 52**.

[0088] **FIGURE 61** is a sectional view, similar to **FIGURE 57**, illustrating another alternative position of the apparatus of **FIGURE 52**.

[0089] **FIGURE 62** is a transverse sectional view of the apparatus of **FIGURE 61**, taken along lines 62-62 of **FIGURE 61**.

[0090] **FIGURE 63** is a side view, similar to **FIGURE 52**, of another apparatus.

[0091] **FIGURE 64** is a front view, similar to **FIGURE 55**, of the embodiment of **FIGURE 63**.

[0092] **FIGURE 65A** is a sectional view, similar to **FIGURE 57**, of the apparatus of **FIGURE 63**, used in conjunction with additional structure in a patient.

[0093] **FIGURE 65B** is a transverse sectional view of the apparatus of **FIGURE 63**, taken along lines 65B-65B of **FIGURE 65**.

[0094] **FIGURE 66A** is a side elevation view of a first portion of one embodiment of a spinal implant configured to preserve a degree of motion.

[0095] **FIGURE 66B** is a rear or posterior elevation view of the first portion of **FIGURE 66A**.

[0096] **FIGURE 66C** is a bottom or inferior plan view of the first portion of **FIGURE 66A**.

[0097] **FIGURE 67A** is a side or lateral elevation view of a second portion of one embodiment of a spinal implant.

[0098] **FIGURE 67B** is a rear or posterior elevation view of the second portion of **FIGURE 67A**.

[0099] **FIGURE 67C** is a top or superior plan view of the second portion of FIGURE 67A.

[0100] **FIGURE 68A** and **68B** are side elevation views of the spinal implant illustrated by **FIGURES 66A – 67C** wherein the first and second portions are depicted in two different stages of articulation.

[0101] **FIGURES 69A** and **69B** are partial cross-sectional rear elevation views of the implant illustrated in **FIGURES 66A – 67C** wherein the first and second portions are depicted in two different stages of articulation.

[0102] **FIGURES 70A** and **70B** show a perspective view of another embodiment of a spinal implant having a cylindrical form.

[0103] **FIGURE 71** is a cross-sectional side view of the spinal implant of **FIGURES 70A** and **70B**.

[0104] **FIGURE 72** is a cross-sectional end view of the spinal implant of **FIGURES 70A** and **70B**.

[0105] **FIGURE 73** is a plan view of another embodiment of a spinal implant.

[0106] **FIGURE 74** is a plan view of another embodiment of a spinal implant.

[0107] **FIGURE 75** is a plan view of another embodiment of a spinal implant.

[0108] **FIGURE 76** is a schematic view of one surface of a vertebra that defines one end of an interbody space and one embodiment of an access device configured to provide access to the interbody space.

[0109] **FIGURE 76A** is a cross-section view of a proximal portion of one embodiment of the access device of **FIGURE 76**.

[0110] **FIGURE 76B** is a cross-section view of a proximal portion of another embodiment of the access device of **FIGURE 76**.

[0111] **FIGURE 77** is a schematic lateral view of a portion of a spine with the access device of **FIGURE 76B** applied thereto to provide access to an interbody space.

[0112] **FIGURE 78** is a schematic view similar to that of **FIGURE 76** illustrating one method of inserting a spinal implant into an interbody space through an access device.

[0113] **FIGURE 79** is a schematic view similar to that of **FIGURE 77** showing a spinal implant configured to preserve or restore motion inserted into an interbody space.

[0114] **FIGURE 80** is a schematic posterior view of a portion of a spine with an access device applied thereto to insert a guide to an interbody space.

[0115] **FIGURE 81** is a perspective view of one embodiment of a guide attached to a vertebra, facilitating access to an interbody space.

[0116] **FIGURE 82A** is a view of one method of preparing an interbody space for the insertion of a spinal implant into an interbody space using a guide.

[0117] **FIGURE 82B** is a cross-sectional view of a path shown in **FIGURE 84A**.

[0118] **FIGURE 82C** is a lateral view of a portion of a spine with an access device, guide and mill applied thereto for preparing an interbody space for a spinal implant.

[0080] **FIGURE 83** is a perspective view of a replacement disc nucleus comprising a compliant enclosure;

[0119] **FIGURE 84A** is a perspective view of a replacement disc nucleus that incorporates a hydrogel;

[0120] **FIGURE 84B** is a side, sectional view of the replacement spinal disc nucleus of **FIGURE 84A** along the line 84B– 84B;

[0121] **FIGURE 84C** is a top, sectional view of the replacement spinal disc nucleus of **FIGURE 84A** along the line 84C – 84C;

[0122] **FIGURE 85** is a perspective view of the replacement spinal disc nucleus of **FIGURE 84A** in a hydrated state;

[0123] **FIGURE 86** is a schematic diagram of a spine of a patient with one embodiment of a replacement disc nucleus implanted therein;

[0124] **FIGURE 87** is a plan view of the replacement disc nucleus of **FIGURE 86**;

[0125] **FIGURE 88** is a diagram representing the spine of a patient with another embodiment of a replacement disc nucleus implanted therein;

[0126] **FIGURE 89** is a perspective view illustrating one embodiment of a replacement disc nucleus;

[0127] **FIGURE 90** is a schematic view of one surface of a vertebra that defines one end of an intervertebral space and one embodiment of an access device configured to provide access to the intervertebral space;

[0128] **FIGURE 91** is a schematic lateral view of a portion of a spine with the access device of **FIGURE 90** applied thereto to provide access to an intervertebral space;

[0129] **FIGURE 92** is a schematic view similar to that of **FIGURE 90** illustrating one method of preparing an intervertebral space through an access device for the insertion of a replacement disc nucleus;

[0130] **FIGURE 93** is a schematic view similar to that of **FIGURE 90** illustrating one method of inserting a replacement disc nucleus into an intervertebral space through an access device

[0131] **FIGURE 94** is a schematic view similar to that of **FIGURE 90** illustrating another method of inserting a replacement disc nucleus into an intervertebral space through an access device; and

[0132] **FIGURE 95** is a schematic view similar to that of **FIGURE 90** showing additional embodiments of devices that may be used in conjunction with the insertion of a replacement disc nucleus.

[0133] **FIGURE 96** is a schematic view of one embodiment of a dynamic stabilization device shown applied to a spine of a patient;

[0134] **FIGURE 97** is a partial cross-sectional view of a portion of the dynamic stabilization device of **FIGURE 96**;

[0135] **FIGURE 98** is a detail view of a portion of the dynamic stabilization device of **FIGURE 96**;

[0136] **FIGURE 99** is an elevation view illustrating one embodiment of a dynamic stabilization device applied to a human spine;

[0137] **FIGURE 100** is a lateral elevation view illustrating one embodiment of a dynamic stabilization device applied to a human spine;

[0138] **FIGURE 101** is a detail view illustrating one embodiment of a dynamic stabilization device;

[0139] **FIGURE 102** is a perspective view illustrating one embodiment of a dynamic stabilization device applied to a human spine;

[0140] **FIGURE 103** is an elevation view illustrating one embodiment of a dynamic stabilization device applied to a human spine;

[0141] **FIGURE 104** is a schematic view of one embodiment of an access device applied through the skin of a patient to provide access to a surgical location near the spine in connection with a dynamic stabilization procedure;

[0142] **FIGURE 105** is a lateral view of two adjacent vertebrae of the spine to which the access device of **FIGURE 104** has been applied, illustrating the application of one embodiment of a dynamic stabilizer;

[0143] **FIGURE 106** is a lateral view of two adjacent vertebrae of the spine to which the access device of **FIGURE 104** has been applied, illustrating the application of another embodiment of a dynamic stabilizer; and

[0144] **FIGURE 107** is a lateral view of two adjacent vertebrae of the spine to which the access device of **FIGURE 104** has been applied, illustrating the application of another embodiment of a dynamic stabilizer.

[0145] **FIGURE 108** is a view illustrating the placement of an access device in one embodiment of a fixation method.

[0146] **FIGURE 109** is a view illustrating one embodiment of a fixation method.

[0147] **FIGURE 110** is a view illustrating one embodiment of a fixation method.

[0148] **FIGURE 111** is a view of the spine illustrating a method for creating a translaminar tunnel.

[0149] **FIGURE 112** is a view of the spine illustrating a translaminar tunnel opening.

[0150] **FIGURE 113** is a view of the spine showing a fastener being inserted in a transfacet fixation technique.

[0151] **FIGURE 114** is a view of two fasteners fully secured through the spine in one embodiment of a transfacet fixation method.

[0152] **FIGURE 115** is view illustrating a possible placement of an access device for one embodiment of a fixation method.

[0153] **FIGURE 116** is a view illustrating one embodiment of a fixation method.

[0154] **FIGURE 117** is a view illustrating one embodiment of a fixation method.

[0155] **FIGURE 118** is a schematic illustration of a surgical instrument constructed in accordance with the present invention.

[0156] **FIGURE 119** is an enlarged schematic view of a stem of the surgical instrument of **FIGURE 118**.

[0157] **FIGURE 120** is a schematic sectional view taken along line 3--3 of **FIGURE 119**.

[0158] Throughout the figures, the same reference numerals and characters, unless otherwise stated, are used to denote like features, elements, components or portions of the illustrated embodiments. Moreover, while the subject invention will now be described in detail with reference to the figures, it is done so in connection with the illustrative embodiments. It is intended that changes and modifications can be made to the described embodiments without departing from the true scope and spirit of the subject invention as defined by the appended claims.

Detailed Description of the Preferred Embodiments

[0159] As should be understood in view of the following detailed description, this application is primarily directed to apparatuses and methods providing access to and for treating the spine of a patient. The apparatuses described below provide access to surgical locations at or near the spine and provide a variety of tools useful treating the spine. In particular, various embodiments described hereinbelow include access

devices that are particularly well adapted to be coupled with one or more viewing elements. In some embodiments, access devices are provided that are configured to receive one or more viewing elements at discrete locations about a passage defined by the access device. The apparatuses described herein enable a surgeon to perform a wide variety of methods of treatment as described herein.

I. SYSTEMS FOR PERFORMING PROCEDURES AT A SURGICAL LOCATION

[0160] Various embodiments of apparatuses and procedures described herein will be discussed in terms of minimally invasive procedures and apparatuses, e.g., of endoscopic apparatuses and procedures. However, various embodiments may find use in conventional, open, and mini-open procedures. As used herein, the term "proximal," as is traditional, refers to the end portion of an apparatus that is closest to the operator, while the term "distal" refers to the end portion that is farthest from the operator.

[0161] **FIGURE 1** shows one embodiment of a surgical system 10 that can be used to perform a variety of methods or procedures. In one embodiment, as discussed more fully below, the patient P is placed in the prone position on operating table T, taking care that the abdomen is not compressed and physiological lordosis is preserved. The physician D is able to access the surgical site and perform the surgical procedure with the components of the system 10, which will be described in greater detail herein. The system 10 may be supported, in part, by a mechanical support arm A, such as the type generally disclosed in U.S. Patent No. 4,863,133, which is hereby incorporated by reference herein in its entirety. One mechanical arm of this type is manufactured by Leonard Medical, Inc., 1464 Holcomb Road, Huntington Valley, PA, 19006. The mechanical support arm A is sometimes referred to as a "flex arm." As discussed in greater detail below, the mechanical support arm A is coupled with at least one of an access device and a viewing element.

[0162] The term "access device" is used in its ordinary sense to mean a device that can provide access and is a broad term and it includes structures having an elongated dimension and defining a passage, e.g., a cannula or a conduit. The access device is configured to be inserted through the skin of the patient to provide access during a surgical procedure to a surgical location within a patient, e.g., a spinal location. The term "surgical location" is used in its ordinary sense (i.e. a location where a surgical procedure is performed) and is a broad term and it includes locations subject to or affected by a surgery. The term "spinal location" is used in its ordinary sense (i.e. a location at or near a spine) and is a broad term and it includes locations adjacent to or associated with a spine that may be sites for surgical spinal procedures. The access device also can retract tissue to provide greater access to the surgical location. The term "retractor" is used in its ordinary sense to mean a device that can displace tissue and is a broad term and it includes structures having an elongated dimension and defining a passage, e.g., a cannula or a conduit, to retract tissue.

[0163] Visualization of the surgical site may be achieved in any suitable manner, e.g., by direct visualization, or by use of a viewing element, such as an endoscope, a camera, loupes, a microscope, or any

other suitable viewing element, or a combination of the foregoing. The term "viewing element" is used in its ordinary sense to mean a device useful for viewing and is a broad term and it also includes elements that enhance viewing, such as, for example, a light source or lighting element. In one embodiment, the viewing element provides a video signal representing images, such as images of the surgical site, to a monitor M. The viewing element may be an endoscope and camera that captures images to be displayed on the monitor M whereby the physician D is able to view the surgical site as the procedure is being performed. The endoscope and camera will be described in greater detail herein.

[0164] The systems are described herein in connection with minimally invasive postero-lateral spinal surgery. One such procedure is a two level postero-lateral fixation and fusion of the spine involving the L4, L5, and S1 vertebrae. In the drawings, the vertebrae will generally be denoted by reference letter V. The usefulness of the apparatuses and procedures is neither restricted to the postero-lateral approach nor to the L4, L5, and S1 vertebrae. The apparatuses and procedures may be used in other anatomical approaches and with other vertebra(e) within the cervical, thoracic, and lumbar regions of the spine. The procedures may be directed toward surgery involving one or more vertebral levels. Some embodiments are useful for anterior and/or lateral procedures. A retroperitoneal approach can also be used with some embodiments. In one retroperitoneal approach, an initial transverse incision is made just left of the midline, just above the pubis, about 3 centimeters in length. The incision can be carried down through the subcutaneous tissues to the anterior rectus sheath, which is incised transversely and the rectus is retracted medially. At this level, the posterior sheath, where present, can be incised. With blunt finger dissection, the retroperitoneal space can be entered. The space can be enlarged with blunt dissection or with a retroperitoneal balloon dissector. The peritoneal sack can be retracted, e.g., by one of the access devices described herein.

[0165] It is believed that embodiments of the invention are also particularly useful where any body structures must be accessed beneath the skin and muscle tissue of the patient, and/or where it is desirable to provide sufficient space and visibility in order to manipulate surgical instruments and treat the underlying body structures. For example, certain features or instrumentation described herein are particularly useful for minimally invasive procedures, e.g., arthroscopic procedures. As discussed more fully below, one embodiment of an apparatus described herein provides an access device that is expandable, e.g., including an expandable distal portion. In addition to providing greater access to a surgical site than would be provided with a device having a constant cross-section from proximal to distal, the expandable distal portion prevents or substantially prevents the access device, or instruments extended therethrough to the surgical site, from dislodging or popping out of the operative site.

A. Systems and Devices for Establishing Access

[0166] In one embodiment, the system 10 includes an access device that provides an internal passage for surgical instruments to be inserted through the skin and muscle tissue of the patient P to the surgical site. The access device preferably has a wall portion defining a reduced profile, or low-profile,

configuration for initial percutaneous insertion into the patient. This wall portion may have any suitable arrangement. In one embodiment, discussed in more detail below, the wall portion has a generally tubular configuration that may be passed over a dilator that has been inserted into the patient to atraumatically enlarge an opening sufficiently large to receive the access device therein.

[0167] The wall portion of the access device preferably can be subsequently expanded to an enlarged configuration, by moving against the surrounding muscle tissue to at least partially define an enlarged surgical space in which the surgical procedures will be performed. In a sense, it acts as its own dilator. The access device may also be thought of as a retractor, and may be referred to herein as such. Both the distal and proximal portion may be expanded, as discussed further below. However, the distal portion preferably expands to a greater extent than the proximal portion, because the surgical procedures are to be performed at the surgical site, which is adjacent the distal portion when the access device is inserted into the patient.

[0168] While in the reduced profile configuration, the access device preferably defines a first unexpanded configuration. Thereafter, the access device can enlarge the surgical space defined thereby by engaging the tissue surrounding the access device and displacing the tissue outwardly as the access device expands. The access device preferably is sufficiently rigid to displace such tissue during the expansion thereof. The access device may be resiliently biased to expand from the reduced profile configuration to the enlarged configuration. In addition, the access device may also be manually expanded by an expander device with or without one or more surgical instruments inserted therein, as will be described below. The surgical site preferably is at least partially defined by the expanded access device itself. During expansion, the access device can move from a first overlapping configuration to a second overlapping configuration in some embodiments.

[0169] In some embodiments, the proximal and distal portions are separate components that may be coupled together in a suitable fashion. For example, the distal end portion of the access device may be configured for relative movement with respect to the proximal end portion in order to allow the physician to position the distal end portion at a desired location. This relative movement also provides the advantage that the proximal portion of the access device nearest the physician D may remain substantially stable during such distal movement. In one embodiment, the distal portion is a separate component that is pivotally or movably coupled to the proximal portion. In another embodiment, the distal portion is flexible or resilient in order to permit such relative movement.

1. Access Devices

[0170] One embodiment of an access device is illustrated in **FIGURES 2-6** and designated by reference number 20. In one embodiment, the access device 20 includes a proximal wall portion 22 that has a tubular configuration, and a distal wall portion that has an expandable skirt portion 24. The skirt portion 24 preferably is enlargeable from a reduced profile configuration having an initial dimension 26 (illustrated in

FIGURE 2) and corresponding cross-sectional area, to an enlarged configuration having a second dimension 28 (illustrated in **FIGURE 4**) and corresponding cross-sectional area. In one embodiment, the skirt portion 24 is coupled to the proximal wall portion 22 with a rivet 30, pin, or similar connecting device to permit movement of the skirt portion 24 relative to the proximal wall portion 22.

[0171] In the illustrated embodiment, the skirt portion 24 is manufactured from a resilient material, such as stainless steel. The skirt portion 24 preferably is manufactured so that it normally assumes an expanded configuration as illustrated in **FIGURE 4**. With reference to **FIGURE 3**, the skirt portion 24 may assume an intermediate dimension 34 and corresponding cross-sectional area, which is greater than the initial dimension 26 of the reduced profile configuration of **FIGURE 2**, and smaller than the dimension 28 of the enlarged configuration of **FIGURE 4**. The skirt portion 24 may assume the intermediate configuration of **FIGURE 3** when deployed in the patient in response to the force of the tissue acting on the skirt portion 24. The intermediate dimension 34 can depend upon several factors, such as the rigidity of the skirt portion 24, the surrounding tissue, and whether such surrounding tissue has relaxed or tightened during the course of the procedure. An outer sleeve 32 (illustrated in dashed line in **FIGURE 2**) may be provided. Preferably, the outer sleeve surrounds the access device 20 and maintains the skirt portion 24 in the reduced profile configuration prior to insertion into the patient. The outer sleeve 32 may be made of plastic. Where provided, the outer sleeve 32 preferably is configured to be easily deployed. For example, a release device may be provided that releases or removes the outer sleeve 32 upon being operated by the user. In one embodiment, a braided polyester suture is embedded within the sleeve 32, aligned substantially along the longitudinal axis thereof. In use, when the suture is withdrawn, the outer sleeve 32 is torn, allowing the access device 20 to resiliently expand from the reduced profile configuration of **FIGURE 2** to the expanded configurations of **FIGURES 3-4**. While in the reduced profile configuration of **FIGURE 2**, the skirt portion 24 defines a first overlapping configuration 33, as illustrated by the dashed line. As the skirt portion 24 resiliently expands, the skirt portion 24 assumes the expanded configuration, as illustrated in **FIGURES 3-4**.

[0172] The skirt portion 24 preferably is sufficiently rigid that it is capable of displacing the tissue surrounding the skirt portion 24 as it expands. Depending upon the resistance exerted by surrounding tissue, the skirt portion 24 preferably is sufficiently rigid to provide some resistance against the tissue to remain in the configurations of **FIGURES 3-4**. Moreover, the expanded configuration of the skirt portion 24 is at least partially supported by the body tissue of the patient. The rigidity of the skirt portion 24 and the greater expansion at the distal portion preferably creates a stable configuration that is at least temporarily stationary in the patient. This arrangement preferably frees the physician from the need to actively support the access device 20, e.g., prior to adding an endoscope mount platform 300 and a support arm 400 (see **FIGURES 21-22**).

[0173] One embodiment of the skirt portion 24 of the access device 20 is illustrated in an initial flattened configuration in **FIGURE 5**. The skirt portion 24 may be manufactured from a sheet of stainless steel

having a thickness of about 0.007 inches. In various embodiments, the dimension 28 of the skirt portion 24 is about equal to or greater than 50 mm, is about equal to or greater than 60 mm, is about equal to or greater than 70 mm, is about equal to or greater than 80 mm, or is any other suitable size, when the skirt portion 24 is in the enlarged configuration. In one embodiment, the dimension 28 is about 63 mm, when the skirt portion 24 is in the enlarged configuration. The unrestricted shape of the skirt portion 24 is a circular shape in one embodiment and is an oblong shape in another embodiment. In another embodiment, the skirt portion 24 has an oval shape, wherein the dimension 28 defines a longer dimension of the skirt portion 24 and would be about 85 mm. In another embodiment, the skirt portion 24 has an oval shape and the dimension 28 defines a longer dimension of the skirt portion 24 of about 63 mm. An increased thickness, e.g., about 0.010 inches, may be used in connection with skirt portions having a larger diameter, such as about 65 mm. Other materials, such as nitinol or plastics having similar properties, may also be useful.

[0174] As discussed above, the skirt portion 24 preferably is coupled to the proximal wall portion 22 with a pivotal connection, such as rivet 30. A pair of rivet holes 36 can be provided in the skirt portion 24 to receive the rivet 30. The skirt portion 24 also has two free ends 38 and 40 in one embodiment that are secured by a slidable connection, such as a second rivet 44 (not shown in **FIGURE 5**, illustrated in **FIGURES 2-4**). A pair of complementary slots 46 and 48 preferably are defined in the skirt portion 24 adjacent the free ends 38 and 40. The rivet 44 is permitted to move freely within the slots 46 and 48. This slot and rivet configuration allows the skirt portion 24 to move between the reduced profile configuration of **FIGURE 2** and the enlarged or expanded configurations of **FIGURES 3-4**. The use of a pair of slots 46 and 48 reduces the risk of the "button-holing" of the rivet 44, e.g., a situation in which the opening of the slot becomes distorted and enlarged such that the rivet may slide out of the slot, and cause failure of the device. The likelihood of such occurrence is reduced in skirt portion 24 because each of the slots 46 and 48 in the double slot configuration has a relatively shorter length than a single slot configuration. Being shorter, the slots 46, 48 are less likely to be distorted to the extent that a rivet may slide out of position. In addition, the configuration of rivet 44 and slots 46 and 48 permits a smoother operation of enlarging and reducing the skirt portion 24, and allows the skirt portion 24 to expand to span three or more vertebrae, e.g., L4, L5, and S1. This arrangement enables multi-level procedures, such as multilevel fixation procedures alone or in combination with a variety of other procedures, as discussed below. Other embodiments include a single slot rather than the slots 46, 48, or more than two slots.

[0175] An additional feature of the skirt portion 24 is the provision of a shallow concave profile 50 defined along the distal edge of the skirt portion 24, which allows for improved placement of the skirt portion 24 with respect to the body structures and the surgical instruments defined herein. In one embodiment, a pair of small scalloped or notched portions 56 and 58, are provided, as illustrated in **FIGURE 5**. When the skirt portion 24 is assembled, the notched portions 56 and 58 are generally across from each other. When the skirt portion 24 is applied to a patient, the notched portions 56, 58 are oriented in the ceph-

caudal direction (indicated by a dashed line 60 in **FIGURE 4**). In this arrangement, instruments and implants, such as an elongated member 650 used in a fixation procedure (described in detail below), may extend beyond the area enclosed by the skirt portion 24 without moving or raising the skirt portion 24, e.g., by allowing the elongated member 650 (or other implant or instrument) to pass under the skirt portion 24. The notched portions 56, 58 also enable the elongated member 650 (or other implant or instrument) to extend beyond the portion of the surgical space defined within the outline of the distal end of the skirt portion 24. The notched portions 56, 58 are optional, as illustrated in connection with another embodiment of an access device 54, illustrated in **FIGURE 6**, and may be eliminated if, for example, the physician deems the notches to be unnecessary for the procedures to be performed. For example, in some fixation procedures such extended access is not needed, as discussed more fully below. As illustrated in **FIGURE 4**, the skirt portion 24 may be expanded to a substantially conical configuration having a substantially circular or elliptical profile.

[0176] Furthermore, it is contemplated that the skirt portion 24 of the access device 20 can include a stop that retains the skirt portion in an expanded configuration, as shown in U.S. Patent Application Serial No. 10/361,887, filed February 10, 2003, now U.S. Application Patent Publication No. US2003/153927 A1, which is hereby incorporated by reference in its entirety herein.

[0177] With reference to **FIGURES 7-12**, another embodiment of an access device 100 comprises an elongate body 102 defining a passage 104 and having a proximal end 106 and a distal end 108. The elongate body 102 has a proximal portion 110 and a distal portion 112. The proximal portion 110 has an oblong or generally oval shaped cross section in one embodiment. The term "oblong" is used in its ordinary sense (i.e., having an elongated form) and is a broad term and it includes a structure having a dimension, especially one of two perpendicular dimensions, such as, for example, width or length, that is greater than another and includes shapes such as rectangles, ovals, ellipses, triangles, diamonds, trapezoids, parabolas, and other elongated shapes having straight or curved sides. The term "oval" is used in its ordinary sense (i.e., egg like or elliptical) and is a broad term and includes oblong shapes having curved portions.

[0178] The proximal portion 110 comprises an oblong, generally oval shaped cross section over the elongated portion. It will be apparent to those of skill in the art that the cross section can be of any suitable oblong shape. The proximal portion 110 can be any desired size. The proximal portion 110 can have a cross-sectional area that varies from one end of the proximal portion to another end. For example, the cross-sectional area of the proximal portion can increase or decrease along the length of the proximal portion 110. Preferably, the proximal portion 110 is sized to provide sufficient space for inserting multiple surgical instruments through the elongate body 102 to the surgical location. The distal portion 112 preferably is expandable and comprises first and second overlapping skirt members 114, 116. The degree of expansion of the distal portion 112 is determined by an amount of overlap between the first skirt member 114 and the second skirt member 116 in one embodiment.

[0179] The elongate body 102 of the access device 100 has a first location 118 distal of a second location 120. The elongate body 102 preferably is capable of having a configuration when inserted within the patient wherein the cross-sectional area of the passage 104 at the first location 118 is greater than the cross-sectional area of the passage 104 at the second location 120. The passage 104 preferably is capable of having an oblong shaped cross section between the second location 120 and the proximal end 106. In some embodiments the passage 104 preferably is capable of having a generally elliptical cross section between the second location 120 and the proximal end 106. Additionally, the passage 104 preferably is capable of having a non-circular cross section between the second location 120 and the proximal end 106. Additionally, in some embodiments, the cross section of the passage 104 can be symmetrical about a first axis and a second axis, the first axis being generally normal to the second axis.

[0180] In another embodiment, an access device comprises an elongate body defining a passage and having a proximal end and a distal end. The elongate body can be a unitary structure and can have a generally uniform cross section from the proximal end to the distal end. In one embodiment, the elongate body preferably has an oblong or generally oval shaped cross section along the entire length of the elongate body. The passage can have a generally elliptical cross section between the proximal end and the distal end. The elongate body preferably has a relatively fixed cross-sectional area along its entire length. In one embodiment, the elongate body is capable of having a configuration when inserted within the patient wherein the cross-sectional area of the passage at a first location is equal to the cross-sectional area of the passage at a second location. The passage preferably is capable of having an oblong shaped cross section between the first and second locations. The cross section of the passage can be of any suitable oblong shape and the elongate body can be any desired size. Preferably, the elongate body is sized to provide sufficient space for inserting multiple surgical instruments sequentially or simultaneously through the elongate body to the surgical location.

[0181] In one embodiment, the access device has a uniform, generally oblong shaped cross section and is sized or configured to approach, dock on, or provide access to, anatomical structures. The access device preferably is configured to approach the spine from a posterior position or from a postero-lateral position. A distal portion of the access device can be configured to dock on, or provide access to, posterior portions of the spine for performing spinal procedures, such as, for example, fixation, fusion, or any other procedure described herein. In one embodiment, the distal portion of the access device has a uniform, generally oblong shaped cross section and is configured to dock on, or provide access to, generally posterior spinal structures. Generally posterior spinal structures can include, for example, one or more of the transverse process, the superior articular process, the inferior articular process, and the spinous process. In some embodiments, the access device can have a contoured distal end to facilitate docking on one or more of the posterior spinal structures. Accordingly, in one embodiment, the access device has a uniform,

generally oblong shaped cross section with a distal end sized, configured, or contoured to approach, dock on, or provide access to, spinal structures from a posterior or postero-lateral position.

[0182] Further details and features pertaining to access devices and systems are described in U.S. Patent Application No. 09/772,605, filed January 30, 2001, Application No. 09/906,463, filed July 16, 2001, Application No. 10/361,887, filed February 10, 2003, Application No. 10/280,489, filed October 25, 2002, Application No. 10/678,744 filed October 2, 2003, Application No. 60/513,796, filed October 22, 2003, Application No. 60/514,559, filed October 24, 2003, and Application No. 60/558,296, filed March 31, 2004 which are incorporated by reference in their entireties herein.

2. Dilators and Expander Devices

[0183] According to one application or procedure, an early stage involves determining a point in the skin of the patient at which to insert the access device 20. The access point preferably corresponds to a posterior-lateral aspect of the spine. Manual palpation and Anterior-Posterior (AP) fluoroscopy may be used to determine preferred or optimal locations for forming an incision in the skin of the patient. In one application, the access device 20 preferably is placed midway (in the cephcaudal direction) between the L4 through S1 vertebrae, centrally about 4-7 cm from the midline of the spine.

[0184] After the above-described location is determined, an incision is made at the location. A guide wire (not shown) is introduced under fluoroscopic guidance through the skin, fascia, and muscle to the approximate surgical site. A series of dilators is used to sequentially expand the incision to the desired width, about 23 mm in one procedure, preferably minimizing damage to the structure of surrounding tissue and muscles. A first dilator can be placed over the guide wire to expand the opening. The guide wire may then be removed. A second dilator, slightly larger than the first dilator, is placed over the first dilator to expand the opening further. Once the second dilator is in place, the first dilator may be removed. This process of (1) introducing a next-larger-sized dilator coaxially over the previous dilator and (2) optionally removing the previous dilator(s) when the next-larger-sized dilator is in place continues until an opening of the desired size is created in the skin, muscle, and subcutaneous tissue. According to one application, the desired opening size is about 23 mm. (Other dimensions of the opening, e.g., about 20 mm, about 27 mm, about 30 mm, etc., are also useful with this apparatus in connection with spinal surgery, and still other dimensions are contemplated.)

[0185] **FIGURE 13** shows that following placement of a dilator 120, which is the largest dilator in the above-described dilation process, the access device 20 is introduced in its reduced profile configuration and positioned over the dilator 120. The dilator 120 is subsequently removed from the patient, and the access device 20 remains in position.

[0186] Once positioned in the patient, the access device 20 may be enlarged to provide a passage for the insertion of various surgical instruments and to provide an enlarged space for performing the procedures described herein. As described above, the access device may achieve the enlargement in

several ways. In one embodiment, a distal portion of the access device may be enlarged, and a proximal portion may maintain a constant diameter. The relative lengths of the proximal portion 22 and the skirt portion 24 may be adjusted to vary the overall expansion of the access device 20. Alternatively, such expansion may extend along the entire length of the access device 20. In one application, the access device 20 may be expanded by removing a suture 35 and tearing the outer sleeve 32 surrounding the access device 20, and subsequently allowing the skirt portion 24 to resiliently expand towards its fully expanded configuration as (illustrated in **FIGURE 4**) to create an enlarged surgical space from the L4 to the S1 vertebrae. The resisting force exerted on the skirt portion 24 may result in the skirt portion 24 assuming the intermediate configuration illustrated in **FIGURE 3**. Under many circumstances, the space created by the skirt portion 24 in the intermediate configuration is a sufficiently large working space to perform the procedure described herein. Once the skirt portion 24 has expanded, the rigidity and resilient characteristics of the skirt portion 24 preferably allow the access device 20 to resist closing to the reduced profile configuration of **FIGURE 2** and to at least temporarily resist being expelled from the incision. These characteristics create a stable configuration for the access device 20 to remain in position in the body, supported by the surrounding tissue. It is understood that additional support may be needed, especially if an endoscope is added.

[0187] According to one embodiment of a procedure, the access device 20 may be further enlarged at the skirt portion 24 using an expander apparatus to create a surgical access space. An expander apparatus useful for enlarging the access device has a reduced profile configuration and an enlarged configuration. The expander apparatus is inserted into the access device in the reduced profile configuration, and subsequently expanded to the enlarged configuration. The expansion of the expander apparatus also causes the access device to be expanded to the enlarged configuration. In some embodiments, the expander apparatus may increase the diameter of the access device along substantially its entire length in a generally conical configuration. In other embodiments, the expander apparatus expands only a distal portion of the access device, allowing a proximal portion to maintain a relatively constant diameter.

[0188] In addition to expanding the access device, in some embodiments the expander apparatus may also be used to position the distal portion of the access device at the desired location for the surgical procedure. The expander can engage an interior wall of the access device to move the access device to the desired location. For embodiments in which the distal portion of the access device is relatively movable with respect to the proximal portion, the expander apparatus is useful to position the distal portion without substantially disturbing the proximal portion.

[0189] In some procedures, an expander apparatus is used to further expand the skirt portion 24 towards the enlarged configuration (illustrated in **FIGURE 4**). The expander apparatus is inserted into the access device, and typically has two or more members that are movable to engage the interior wall of the skirt portion 24 and apply a force sufficient to further expand the skirt portion 24. **FIGURES 14** and **15** show one embodiment of an expander apparatus 200 that has a first component 202 and a second component 204.

The first component 202 and the second component 204 of the expander apparatus 200 are arranged in a tongs-like configuration and are pivotable about a pin 206. The first and second components 202 and 204 can be constructed of steel having a thickness of about 9.7 mm. Each of the first and second components 202 and 204 has a proximal handle portion 208 and a distal expander portion 210. Each proximal handle portion 208 has a finger grip 212 that may extend transversely from an axis, e.g., a longitudinal axis 214, of the apparatus 200. The proximal handle portion 208 may further include a stop element, such as flange 216, that extends transversely from the longitudinal axis 214. The flange 216 preferably is dimensioned to engage the proximal end 25 of the access device 20 when the apparatus 200 is inserted a predetermined depth. This arrangement provides a visual and tactile indication of the proper depth for inserting the expander apparatus 200. In one embodiment, a dimension 218 from the flange 216 to the distal tip 220 is about 106 mm. The dimension 218 is determined by the length of the access device 20, which in turn is a function of the depth of the body structures beneath the skin surface at which the surgical procedure is to be performed. The distal portions 210 are each provided with an outer surface 222 for engaging the inside wall of the skirt portion 24. The outer surface 222 is a frusto-conical surface in one embodiment. The expander apparatus 200 has an unexpanded distal width 224 at the distal tip 220 that is about 18.5 mm in one embodiment.

[0190] In use, the finger grips 212 are approximated towards one another, as indicated by arrows A in **FIGURE 15**, which causes the distal portions 210 to move to the enlarged configuration, as indicated by arrows B. The components 202 and 204 are also provided with a cooperating tab 226 and shoulder portion 228 which are configured for mutual engagement when the distal portions 210 are in the expanded configuration. In the illustrated embodiment, the expander apparatus 200 has an expanded distal width 230 that extends between the distal portions 210. The expanded distal width 230 can be about 65 mm or less, about as large as 83 mm or less, or any other suitable width. The tab 226 and shoulder portion 228 together limit the expansion of the expander apparatus 200 to prevent expansion of the skirt portion 24 of the access device 20 beyond its designed dimension, and to minimize trauma to the underlying tissue. Further features related to the expander apparatus are described in US Patent No. 6,652,553, issued November 25, 2003, which is incorporated by reference in its entirety herein.

[0191] When the access device 20 is inserted into the patient and the outer sleeve 32 is removed, the skirt portion 24 expands to a point where the outward resilient expansion of the skirt portion 24 is balanced by the force of the surrounding tissue. The surgical space defined by the access device 20 may be sufficient to perform any of a number of surgical procedures or combination of surgical procedures described herein. However, if it is desired to expand the access device 20 further, the expander apparatus 200, or a similar device, may be inserted into the access device 20 in the reduced profile configuration until the shoulder portions 216 are in approximation with the proximal end 25 of the skirt portion 24 of the access device 20, as shown in **FIGURE 16**.

[0192] **FIGURE 16** shows the expander apparatus 200 inserted in the access device 20 in the reduced profiled configuration. Expansion of the expander apparatus 200 is achieved by approximating the handle portions 212 (not shown in **FIGURE 16**), which causes the distal portions 210 of the expander apparatus 200 to move to a spaced apart configuration. As the distal portions 210 move apart and contact the inner wall of the skirt portion 24, the rivet 44 is allowed to slide within the slots 46 and 48 of the skirt portion 24, thus permitting the skirt portion 24 to expand. When the distal portions 210 reach the maximum expansion of the skirt portion 24 (illustrated by a dashed line in **FIGURE 17**), the tab 226 and shoulder portion 228 of the expander apparatus 200 come into engagement to prevent further expansion of the tongs-like portions (as illustrated in **FIGURE 15**). Alternatively, the access device 20 may be expanded with another device that can selectively have a reduced profile configuration and an expanded configuration, e.g., a balloon or similar device.

[0193] An optional step in the procedure is to adjust the location of the distal portion of the access device 20 relative to the body structures to be operated on. For example, the expander apparatus 200 may also be used to engage the inner wall of the skirt portion 24 of the access device 20 in order to move the skirt portion 24 of the access device 20 to the desired location. For an embodiment in which the skirt portion 24 of the access device 20 is relatively movable relative to the proximal portion, e.g. by use of the rivet 30, the expander apparatus 200 is useful to position the skirt portion 24 without substantially disturbing the proximal portion 22 or the tissues closer to the skin surface of the patient. As will be described below, the ability to move the distal end portion, e.g., the skirt portion 24, without disturbing the proximal portion is especially beneficial when an additional apparatus is mounted relative to the proximal portion of the access device, as described below. Further details related to the access device and associated systems may be found in U.S. Patent Application Serial No. 10/926,840, filed on August 26, 2004, which is hereby incorporated herein by reference in its entirety.

B. Systems and Devices for Stabilization and Visualization

[0194] Some procedures can be conducted through the access device 20 without any additional peripheral components being connected thereto. In other procedures it may be beneficial to provide at least one of a support device and a viewing element. As discussed more fully below, support devices can be advantageously employed to provide support to peripheral equipment and to surgical tools of various types. Various embodiments of support devices and viewing elements are discussed herein below.

1. Support Devices

[0195] One type of support device that can be coupled with the access device 20 is a device that supports a viewing element. In one embodiment, an endoscope mount platform 300 and indexing arm 400 support an endoscope 500 on the proximal end 25 of the access device 20 for remotely viewing the surgical procedure, as illustrated in **FIGURES 18-21**. The endoscope mount platform 300 may also provide several other functions during the surgical procedure. The endoscope mount platform 300 preferably includes

a base 302 that extends laterally from a central opening 304 in a generally ring-shaped configuration. In one application, the physician views the procedure primarily by observing a monitor, when inserting surgical instruments into the central opening 304. The base 302 advantageously enables the physician by providing a visual indicator (in that it may be observable in the physician's peripheral vision) as well as tactile feedback as instruments are lowered towards the central opening 304 and into the access device 20.

[0196] The endoscope mount platform 300 preferably has a guide portion 306 at a location off-set from the central opening 304 that extends substantially parallel to a longitudinal axis 308. The base 302 can be molded as one piece with the guide portion 306. The base 302 and guide portion 306 may be constructed with a suitable polymer, such as, for example, polyetheretherketone (PEEK).

[0197] The guide portion 306 includes a first upright member 310 that extends upward from the base 302 and a second upright member 312 that extends upward from the base 302. In one embodiment, the upright members 310, 312 each have a respective vertical grooves 314 and 315 that can slidably receive an endoscopic mount assembly 318.

[0198] The endoscope 500 (not shown in **FIGURE 18**) can be movably mounted to the endoscope mount platform 300 with the endoscope mount assembly 318 in one embodiment. The endoscope mount assembly 318 includes an endoscope mount 320 and a saddle unit 322. The saddle unit 322 is slidably mounted within the grooves 314 and 315 in the upright members 310 and 312. The endoscope mount 320 receives the endoscope 500 through a bore 326 which passes through the endoscope mount 320. Part of the endoscope 500 may extend through the access device 20 substantially parallel to longitudinal axis 308 into the patient's body 130, as shown in **FIGURE 25**.

[0199] The endoscope mount 320 is removably positioned in a recess 328 defined in the substantially "U"-shaped saddle unit 322. In one embodiment, the saddle unit 322 is selectively movable in a direction parallel to the longitudinal axis 308 in order to position the endoscope 500 at the desired height within the access device 20. The movement of the endoscope 500 by way of the saddle unit 322 also advantageously enables the physician to increase visualization of a particular portion of the surgical space defined by the access device, e.g., by way of a zoom feature, as required for a given procedure or a step of a procedure.

[0200] In one embodiment, an elevation adjustment mechanism 340, which may be a screw mechanism, is positioned on the base 302 between the upright members 310 and 312. The elevation adjustment mechanism 340 can be used to selectively move a viewing element, e.g., the endoscope 500 by way of the saddle unit 322. In one embodiment, the elevation adjustment mechanism 340 comprises a thumb wheel 342 and a spindle 344. The thumb wheel 343 is rotatably mounted in a bore in the base 302. The thumb wheel 342 has an external thread 346 received in a cooperating thread in the base 302. The spindle 344 is mounted for movement substantially parallel to the central axis 308. The spindle 344 preferably has a first end received in a rectangular opening in the saddle unit 322, which inhibits rotational movement of the

spindle 344. The second end of the spindle 344 has an external thread that cooperates with an internal thread formed in a bore within the thumb wheel 342. Rotation of the thumb wheel 342 relative to the spindle 344, causes relative axial movement of the spindle unit 344 along with the saddle unit 322. Further details and features related to endoscope mount platforms are described in US Patents No. 6,361,488, issued March 26, 2002; 6,530,880, issued March 11, 2003, and U.S. Patent Application No. 09/940,402, filed August 27, 2001, published as Publication No. 2003/0040656 on February 27, 2003, which are incorporated by reference in their entireties herein.

[0201] **FIGURES 19-21** show that the endoscope mount platform 300 is mountable to the support arm 400 in one embodiment. The support arm 400, in turn, preferably is mountable to a mechanical support, such as mechanical support arm A, discussed above in connection with **FIGURE 1**. The support arm 400 preferably rests on, or is otherwise coupled to, the proximal end 25 of the access device 20. In one embodiment, the support arm 400 is coupled with an indexing collar 420, which is configured to be received in the central opening 304 of the base 302 of endoscope mount platform 300. The indexing collar 420 is substantially toroidal in section and has an outer peripheral wall surface 422, an inner wall surface 424, and a wall thickness 426 that is the distance between the wall surfaces 422, 424. The indexing collar 420 further includes a flange 428, which supports the indexing collar 420 on the support arm 400.

[0202] In one embodiment, a plurality of collars 420 may be provided to make the surgical system 10 modular in that different access devices 20 may be used with a single endoscope mount platform 300. For example, access devices 20 of different dimensions may be supported by providing indexing collars 420 to accommodate each access device size while using a single endoscope mount platform 300. The central opening 304 of the endoscope mount platform 300 can have a constant dimension, e.g., a diameter of about 32.6 mm. An appropriate indexing collar 420 is selected, e.g., one that is appropriately sized to support a selected access device 20. Thus, the outer wall 422 and the outer diameter 430 are unchanged between different indexing collars 420, although the inner wall 424 and the inner diameter 432 vary to accommodate differently sized access devices 20.

[0203] The indexing collar 420 can be mounted to the proximal portion of the access device 20 to allow angular movement of the endoscope mount platform 300 with respect thereto about the longitudinal axis 308 (as indicated by an arrow C in **FIGURE 19**). The outer wall 422 of the index collar 420 includes a plurality of hemispherical recesses 450 that can receive one or more ball plungers 350 on the endoscope mount platform 300 (indicated in dashed line). This arrangement permits the endoscope mount platform 300, along with the endoscope 500, to be fixed in a plurality of discrete angular positions.

[0204] Further details and features related to support arms and indexing collars are described in US Patent No. 6,361,488, issued March 26, 2002, U.S. Patent No. 6,530,880 issued March 11, 2003, and Application 09/940,402 filed August 27, 2001, published as Publication No. 2003/0040656 on February 27, 2003, which are incorporated by reference in their entireties herein.

2. Viewing Elements

[0205] As discussed above, a variety of viewing elements and visualization techniques are embodied in variations of the surgical system 10. One viewing element that is provided in one embodiment is an endoscope.

[0206] **FIGURE 22** shows one embodiment of the endoscope 500 that has an elongated configuration that extends into the access device 20 in order to enable viewing of the surgical site. In particular, the endoscope 500 has an elongated rod portion 502 and a body portion 504. The rod portion 502 extends generally perpendicularly from the body portion 504. In one embodiment, the rod portion 502 of endoscope 500 has a diameter of about 4 mm and a length of about 106 mm. Body portion 504 may define a tubular portion 506 configured to be slidably received in the bore 326 of endoscope mount 320 as indicated by an arrow D. The slidable mounting of the endoscope 500 on the endoscope mount platform 300 permits the endoscope 500 to adjust to access device configurations that have different diameters. Additional mobility of the endoscope 500 in viewing the surgical site may be provided by rotating the endoscope mount platform 300 about the central axis 308 (as indicated by arrow C in **FIGURE 19**).

[0207] The rod portion 502 supports an optical portion (not shown) at a distal end 508 thereof. In one embodiment, the rod portion 502 defines a field of view of about 105 degrees and a direction of view 511 of about 25-30 degrees. An eyepiece 512 preferably is positioned at an end portion of the body portion 504. A suitable camera (not shown) preferably is attached to the endoscope 500 adjacent the eyepiece 512 with a standard coupler unit. A light post 510 can supply illumination to the surgical site at the distal end portion 508. A preferred camera for use in the system and procedures described herein is a three chip unit that provides greater resolution to the viewed image than a single chip device.

[0208] **FIGURES 23A, 23B, 23C, 24A, 24B, and 24C** illustrate other embodiments of support devices and viewing elements. **FIGURES 23A, 23B, and 23C** illustrate one embodiment of a lighting element 520 coupled with a support arm 522 compatible with an access device 524 having a proximal portion with a generally circular cross section. In other embodiments, support arms can be configured to be coupled with access devices having proximal portions with generally oblong or oval cross sections.

[0209] The support arm 522 preferably is coupled with the access device 524 to provide support for the access device 524 during a procedure. As shown in **FIGURES 23A, 23B, and 23C**, the support arm 522 comprises a pneumatic element 526 for maintaining the support arm 522 in a desired position. Depressing a button 528 coupled with a valve of the pneumatic element 526 releases pressure and allows the support arm 522 and access device 524 to be moved relative the patient 530. Releasing the button 528 of the pneumatic element 526 increases pressure and maintains the access device 524 and support arm 522 in the desired position. The support arm 522, as shown, is configured for use with a mechanical arm using a suction, or a vacuum to maintain the access device in a desired location. One of skill in the art will recognize that various other support arms and mechanical arms can be used. For example, commercially

available mechanical arms having clamping mechanisms can be used as well as suction or pressure based arms.

[0210] The support arm 522 can comprise an inner ring portion 532 and an outer ring portion 534 for surrounding the access device 524 at its proximal end. In the illustrated embodiment, the inner and outer ring portions 532, 534 are fixed relative each other. In other embodiments the inner and outer ring portions 532, 534 can move relative each other. The support arm 522 preferably comprises a lighting element support portion 536. In the illustrated embodiment, the lighting element support portion 536 extends above upper surfaces of the inner and outer ring portions 532, 534. The lighting element support portion 536 can extend from the inner ring portion 532, the outer ring portion 534, or both. The lighting element support portion 536 can have a notch or groove 538 for receiving and supporting the lighting element 520. Additionally, the lighting element support portion 536 can have one or more prongs extending at least partially over the lighting element 520 to hold it in place.

[0211] In the illustrated embodiment, the lighting element 520 has an elongated proximal portion 540 and a curved distal portion 542. The proximal portion 540 of the lighting element 520 preferably is coupled with a light source (not shown). The curved distal portion of the lighting element 520 in one embodiment extends only a short distance into the access device and is configured to direct light from the light source down into the access device 524. In another embodiment, the lighting element 520 can be provided such that it does not extend into the access device. In such an embodiment, the right portions 532 and 534 only partially surround the proximal end of the access device 524. Providing a lighting element 520 for use with the access device 524 preferably allows a user to see down into the access device 524 to view a surgical location. Accordingly, use of a lighting element 520 in some cases, enables the user to perform a procedure, in whole or in part, without the use of an endoscope. In one embodiment, the lighting element 520 enables a surgeon to perform the procedure with the use of microscopes or loupes.

[0212] **FIGURES 24A, 24B, and 24C** illustrate other embodiments of visualization elements. As shown in **FIGURE 24A**, a lighting element 560 comprises a support member 562, an access device insert 564, and fiber optic elements 566. The support member 562 has a proximal end 568, a central portion 570, and a distal end 572. The proximal end 568 preferably has a coupling portion 574 for coupling the support member 562 to a support arm or other support system (not shown). The central portion 570 preferably is coupled with the fiber optic elements 566 to provide support there to. The distal end 572 preferably is coupled with the access device insert 564.

[0213] In the illustrated embodiment, the access device insert 564 is configured to be inserted in an access device having a proximal portion with a generally circular cross section. The access device insert 564 is coupled with the fiber optic elements 566. The fiber optic elements 566 extend down into the access device insert 564 so that the ends of the fiber optic elements 566 can direct light down inside an access device along side portions there of.

[0214] **FIGURES 24B and 24C** illustrate other embodiments of visualization elements similar to the embodiment described with reference to **FIGURE 24A**. In the illustrated embodiments, the access device inserts 564 are configured to be inserted into access devices having proximal portions with generally oblong, or oval, cross sections. As shown in **FIGURE 24B**, the access device insert 564 has a generally oblong or oval shaped cross section. The access device insert 564 is coupled with the fiber optic elements 566 along a longer side surface of the access device insert 564. As shown in **FIGURE 24C**, the access device insert 564 has a generally oblong or oval shaped cross section. The access device insert 564 is coupled with the fiber optic elements 566 along a shorter side surface of the access device insert 564. Use of an illumination element with an expandable access device having an oblong shaped proximal section, in some cases, allows a doctor to perform procedures that would be difficult to perform using an endoscope. Increased visualization of the surgical location through the access device can simplify some procedures. For example, decompression of the contra-lateral side can be achieved more easily in some cases without the use of an endoscope.

C. Apparatuses and Methods for Performing Spinal Procedures

[0215] The surgical assembly 10 described above can be deployed to perform a wide variety of surgical procedures on the spine. In many cases, the procedures are facilitated by inserting the access device and configuring it to provide greater access to a surgical location, as discussed above and by mounting the support arm 400 and the endoscope mount platform 300 on the proximal portion, e.g., on the proximal end 25, of the access device 20 (**FIGURES 1** and **22**). As discussed above, visualization of the surgical location is enhanced by mounting a viewing element, such as the endoscope 500, on the endoscope mount platform 300. Having established increased access to and visualization of the surgical location, a number of procedures may be effectively performed.

[0216] Generally, the procedures involve inserting one or more surgical instruments into the access device 20 to manipulate or act on the body structures that are located at least partially within the operative space defined by the expanded portion of the access device 20. **FIGURE 25** shows that in one method, the skirt portion 24 of access device 20 at least partially defines a surgical site or operative space 90 in which the surgical procedures described herein may be performed. Depending upon the overlap of the skirt portion, the skirt portion may define a surface which is continuous about the perimeter or which is discontinuous, having one or more gaps where the material of the skirt portion does not overlap.

[0217] One procedure performable through the access device 20, described in greater detail below, is a two-level spinal fusion and fixation. Surgical instruments inserted into the access device may be used for debridement and decortication. In particular, the soft tissue, such as fat and muscle, covering the vertebrae may be removed in order to allow the physician to visually identify the various "landmarks," or vertebral structures, which enable the physician to determine the location for attaching a fastener, such a fastener 600, discussed below, or other procedures, as will be described herein. Enabling visual identification

of the vertebral structures enables the physician to perform the procedure while viewing the surgical area through the endoscope, microscope, loupes, or other viewing element, or in a conventional, open manner.

[0218] Tissue debridement and decortication of bone are completed using one or more of a debrider blades, a bipolar sheath, a high speed burr, and any other conventional manual instrument. The debrider blades are used to excise, remove and aspirate the soft tissue. The bipolar sheath is used to achieve hemostasis through spot and bulk tissue coagulation. Additional features of debrider blades and bipolar sheaths are described in U.S. Patent No. 6,193,715, assigned to Medical Scientific, Inc., which is incorporated by reference in its entirety herein. The high speed burr and conventional manual instruments are also used to continue to expose the structure of the vertebrae.

1. Fixation Systems and Devices

[0219] Having increased visualization of the pertinent anatomical structure, various procedures may be carried out on the structures. In one procedure, one or more fasteners are attached to adjacent vertebrae V. As discussed in more detail below, the fasteners can be used to provide temporary or permanent fixation and to provide dynamic stabilization of the vertebrae V. These procedures may combined with other procedures, such as procedures employing other types of implant, e.g., procedures employing fusion devices, prosthetic disc components, or other suitable implants. In some procedures, fasteners are attached to the vertebrae before or after fusion devices are inserted between the vertebrae V. Fusion systems and devices are discussed further below.

[0220] In one application, the desired location and orientation of the fastener is determined before the fastener is applied to the vertebra. The desired location and orientation of the fastener may be determined in any suitable manner. For example, the pedicle entry point of the L5 vertebrae may be located by identifying visual landmarks alone or in combination with lateral and A/P fluoroscopy, as is known in the art. With continued reference to **FIGURE 25**, an entry point 92 into the vertebra V is prepared. In procedure, the entry point 92 may be prepared with an awl 550. The entry point 92 corresponds to the pedicle in one procedure. The entry point 92 may be prepared in any suitable manner, e.g., employing a bone probe, a tap, and a sounder to create and verify the integrity of the prepared vertebra. The sounder, as is known in the art, determines whether the hole that is made is surrounded by bone on all sides, and can be used to confirm that there has been no perforation of the pedicle wall.

[0221] After the hole in the pedicle beneath the entry point 92 is prepared, a fastener may be advanced into the hole. Prior to advancing the fastener, or at any other point during the procedure, it may be desirable to adjust the location of the distal portion of the access device 20. The distal portion of the access device 20 may be adjusted by inserting the expander apparatus 200 into the access device 20, expanding the distal portions 210, and contacting the inner wall of the skirt portion 24 to move the skirt portion 24 to the desired location. This step may be performed while the endoscope 500 is positioned within the access device

20, and without substantially disturbing the location of the proximal portion of the access device 20 to which the endoscope mount platform 300 may be attached.

[0222] **FIGURES 26-27** illustrate one embodiment of a fastener 600 that is particularly applicable in procedures involving fixation. The fastener 600 preferably includes a screw portion 602, a housing 604, a spacer member 606, a biasing member 608, and a clamping member, such as a cap screw 610. The screw portion 602 has a distal threaded portion 612 and a proximal, substantially spherical joint portion 614. The threaded portion 612 is inserted into the hole that extends away from the entry point 92 into the vertebrae, as will be described below. The substantially spherical joint portion 614 is received in a substantially annular, partly spherical recess 616 in the housing 604 in a ball and socket joint relationship (see also **FIGURE 29**).

[0223] As illustrated in **FIGURE 27**, the fastener 600 is assembled by inserting the screw portion 602 into a bore in a passage 618 in the housing 604 until the joint portion 614 engages the annular recess 616. The screw portion 602 is retained in the housing 604 by the spacer member 606 and by the biasing member 608. The biasing member 608 provides a biasing force to drive the spacer member 606 into frictional engagement with the joint portion 614 of the screw member 602 and the annular recess 616 of the housing 604. The biasing provided by the biasing member 602 frictionally maintains the relative positions of the housing 604 with respect to the screw portion 602. The biasing member 608 preferably is selected such that biasing force prevents unrestricted movement of the housing 604 relative to the screw portion 602. However, in some embodiments the biasing force is insufficient to resist the application of force by a physician to move the housing 604 relative to the screw portion 602. In other words, this biasing force is strong enough maintain the housing 604 stationary relative to the screw portion 602, but this force may be overcome by the physician to reorient the housing 604 with respect to the screw member 602, as will be described below.

[0224] In the illustrated embodiment, the biasing member 608 is a resilient ring having a gap 620, which permits the biasing member 608 to radially contract and expand. **FIGURE 27(a)** illustrates that the biasing member 608 may have an arched shape, when viewed end-on. The arched shape of the spring member 608 provides the biasing force, as will be described below. The spacer member 606 and the biasing member 608 are inserted into the housing 604 by radially compressing the biasing member into an annular groove 622 in the spacer member 606. The spacer member 606 and the biasing member 608 are slid into the passage 618 until the distal surface of the spacer member 606 engages the joint portion 614 of the screw portion 602, and the biasing member 608 expands radially into the annular groove 622 in the housing 604. The annular groove 622 in the housing 604 has a dimension 623 that is smaller than the uncompressed height of the arched shape of the biasing member 608. When the biasing member 608 is inserted in the annular groove 620, the biasing member 608 is flattened against its normal bias, thereby exerting the biasing

force to the spacer member 606. It is understood that similar biasing members, such as coiled springs, belleville washers, or the like may be used to supply the biasing force described herein.

[0225] The spacer member 606 is provided with a longitudinal bore 626, which provides access to a hexagonal recess 628 in the proximal end of the joint portion 614 of the screw member 602. The proximal portion of the housing 604 includes a pair of upright members 630 and 631 that are separated by substantially "U"-shaped grooves 632. A recess for receiving elongated member 650 is defined by the pair of grooves 632 between upright members 630 and 631. Elongated member 650 preferably is configured to be placed distally into the housing 604 in an orientation substantially transverse to the longitudinal axis of the housing 604, as will be described below. The inner walls of he upright members 630 and 631 are provided with threads 634 for attachment of the cap screw 610 by threads 613 therein.

[0226] Additional features of the fastener 600 are also described in U.S. Patent Application No. 10/075,668, filed February 13, 2002, published as U.S. Application Publication No. 2003/0153911A1 on Aug. 14, 2003, and Application No. 10/087,489, filed March 1, 2002, published as U.S. Application Publication No. 2003/0167058A1 on September 4, 2003, which are incorporated by reference in their entireties herein.

[0227] According to one application, the fastener 600 is inserted into the access device 20 and guided to the prepared hole at the entry point 92 in the vertebrae. The fastener 600 preferably is simultaneously supported and advanced into the hole so that the fastener 600 is secured in the in the hole beneath the entry point 92. In the illustrated embodiment the fastener 600 is supported and attached to the bone by an endoscopic screwdriver apparatus 660, illustrated in **FIGURES 28-29**. The screwdriver 660 includes a proximal handle portion 662 (illustrated in dashed line), an elongated body portion 664, and a distal tool portion 666.

[0228] The distal tool portion 666, as illustrated in greater detail in **FIGURE 29** includes a substantially hexagonal outer periphery that is received in the substantially hexagonal recess 628 in the joint portion 614 of the screw member 602. A spring member at the distal tool portion 666 releasably engages the hexagonal recess 628 of the screw member 602 to support the fastener 600 during insertion and tightening. In the illustrated embodiment, a spring member 672 is configured to engage the side wall of the recess 628. More particularly, a channel or a groove is provided in the tip portion 666 for receiving the spring member 672. The channel or groove includes a medial longitudinal notch portion 676, a proximal, angled channel portion 678, and a distal substantially transverse channel portion 680. The spring member 672 is preferably manufactured from stainless steel and has a medial portion 682, proximal portion 684, and a transverse distal portion 686. The medial portion 682 is partially received in the longitudinal notch portion 676. The proximal portion 684 preferably is angled with respect to the medial portion 682 and is fixedly received in the angled channel portion 678. The transverse distal portion 686 preferably is slidably received in the transverse channel 680. The medial portion 682 of the spring member 672 is partially exposed from the distal tip portion 666 and normally is biased in a transverse outward direction with respect to the longitudinal axis (indicated by

arrow E), in order to supply bearing force against the wall of the recess 628. Alternatively, the distal tip portion of the screwdriver may be magnetized in order to hold the screw portion 602. Similarly, the distal tip portion may include a ball bearing or similar member which is normally biased in a radially outward direction to engage the interior wall of the recess 628 to secure the fastener 600 to the screwdriver distal tip 666. Other means may be provided for temporarily but securely coupling the fastener 600 with the screwdriver distal tip 666.

[0229] The insertion of the fastener 600 into the prepared hole that extends into the vertebrae from the entry point 92 may be achieved by insertion of screwdriver 660 into access device 20 (indicated by arrow G). This procedure may be visualized by the use of the endoscope 500 in conjunction with fluoroscopy, or by way of any other suitable viewing element. The screw portion 602 is threadedly advanced by the endoscopic screwdriver 660 into the prepared hole that extends beneath the entry point 92 (indicated by arrow H). The endoscopic screwdriver 660 is subsequently separated from the fastener 600, by applying a force in the proximal direction, and thereby releasing the distal tip portion 666 from the hexagonal recess 628 (e.g., causing the transverse distal portion 686 of the spring member 672 to slide within the transverse recess 680 against the bias, indicated by arrow F), and removing the screwdriver 660 from the access device 20. An alternative method may use a guidewire, which is fixed in the hole beneath the entry point 92, and a cannulated screw which has an internal lumen and is guided over the guidewire into the hole beneath the entry point 92. Where a guidewire system is used, the screwdriver also would be cannulated so that the screwdriver would fit over the guidewire.

[0230] For a two-level fixation, it may be necessary to prepare several holes and attach several fasteners 600. Preferably, the access device 20 is sized to provide simultaneous access to all vertebrae in which the surgical procedure is being performed. In some cases, however, additional enlargement or repositioning of the distal portion of the access device 20 may be helpful in providing sufficient access to the outer vertebrae, e.g., the L4 and S1 vertebrae. In the illustrated embodiment, the expander apparatus 200 may be repeatedly inserted into the access device 20 and expanded in order to further open or to position the skirt portion 24. In one procedure, additional fasteners are inserted in the L4 and S1 vertebrae in a similar fashion as the fastener 600 inserted into the L5 vertebra as described above. (When discussed individually or collectively, a fastener and/or its individual components will be referred to by the reference number, e.g., fastener 600, housing 604, and all fasteners 600. However, when several fasteners and/or their components are discussed in relation to one another, an alphabetic subscript will be used, e.g., fastener 600a is moved towards fastener 600b.)

[0231] In one application, after the fasteners 600 are advanced into the vertebrae, the housing portions 604 of the fasteners 600 are substantially aligned such that their upright portions 630 and 631 face upward, and the notches 632 are substantially aligned to receive the elongated member 650 therein. The

frictional mounting of the housing 604 to the screw member 602, described above, allows the housing 604 to be temporarily positioned until a subsequent tightening step is performed, described below.

[0232] Positioning of the housing portions 604 may be performed by the use of an elongated surgical instrument capable of contacting and moving the housing portion to the desired orientation. One such instrument for positioning the housings 604 is a grasper apparatus 700, illustrated in **FIGURE 30**. The grasper apparatus 700 includes a proximal handle portion 702, an elongated body portion 704, and distal nose portion 706. The distal nose portion 706 includes a pair of grasping jaws 708a and 708b, which are pivotable about pin 710 by actuation of the proximal handle portion 702. The grasping jaws 708a and 708b are illustrated in the closed position in **FIGURE 30**. Pivoting the movable handle 714 towards stationary handle 712 causes longitudinal movement of actuator 716, which in turn pivots the jaw 708b towards an open position (illustrated in dashed line). The biasing members 718 and 720 are provided to return the handles 712 and 714 to the open position and bias the jaws 708a and 708b to the closed position.

[0233] In one application, the elongated member 650 is inserted into the access device 20. In one application, the elongated member 650 is manufactured from a biocompatible material and is sufficiently strong to maintain the position of the vertebrae, or other body structures, coupled by the elongate member 650 with little or no relative motion therebetween. In one embodiment, the elongated members 650 are manufactured from Titanium 6/4 or titanium alloy. The elongated member 650 also may be manufactured from stainless steel or any other suitable material. The transverse shape, width (e.g., radii), and lengths of the elongated members 650 are selected by the physician to provide the best fit for the positioning of the screw heads. Such selection may be performed by placing the elongated member 650 on the skin of the patient overlying the location of the fasteners and viewed fluoroscopically. For example, a 70 mm preformed rod having a 3.5" bend radius may be selected for the spinal fixation.

[0234] In one application, the elongated member 650 is fixed to each of the fasteners 600, and more particularly, to the housings 604 of each fastener 600. The grasper apparatus 700, described above, is also particularly useful for inserting the elongated member 650 into the access device 20 and positioning it with respect to each housing 604. As illustrated in **FIGURE 30**, the jaws 708a and 708b of the grasper apparatus 700 each has shaped (e.g., curved) contact portions 722a and 722b for contacting and holding the outer surface of the elongated member 650.

[0235] As illustrated in **FIGURE 31**, the grasper apparatus 700 may be used to insert the elongated member 650 into the operative space 90 defined at least partially by the skirt portion 24 of the access device 20. In some embodiments, the cut-out portions 56 and 58 provided in the skirt portion 24 assist in the process of installing the elongated member 650 with respect to the housings 604. The cut-out portions 56 and 58 allow an end portion 652 of the elongated member 650 to extend beyond the operative space without raising or repositioning the skirt portion 24. The elongated member 650 is positioned within the recesses in each housing 604 defined by grooves 632 disposed between upright members 630 and 631. The

elongated member 650 is positioned in an orientation substantially transverse to the longitudinal axis of each housing 604.

[0236] Further positioning of the elongated member 650 may be performed by guide apparatus 800, illustrated in **FIGURE 32**. Guide apparatus 800 is useful in cooperation with an endoscopic screwdriver, such as endoscopic screwdriver 660 (illustrated in **FIGURE 28**), in order to position the elongated member 650, and to introduce and tighten the cap screw 610, described above and illustrated in **FIGURE 27**. Tightening of the cap screw 610 with respect to the housing 604 fixes the orientation of the housing 604 with respect to the screw portion 602 and fixes the position of the elongated member 650 with respect to the housings 604.

[0237] In the illustrated embodiment, the guide apparatus 800 has a proximal handle portion 802, an elongated body portion 804, and a distal tool portion 806. The elongated body portion 804 defines a central bore 808 (illustrated in dashed line) along its longitudinal axis 810. The central bore 808 is sized and configured to receive the endoscopic screwdriver 660 and cap screw 610 therethrough. In the exemplary embodiment, the diameter of the central bore 808 of the elongated body portion 804 is about 0.384 - 0.388 inches in diameter, and the external diameter of the endoscopic screwdriver 660 (**FIGURE 28**) is about 0.25 inches. The proximal handle portion 802 extends transverse to the longitudinal axis 810, which allows the physician to adjust the guide apparatus 800 without interfering with the operation of the screwdriver 660.

[0238] The distal portion 806 of the apparatus includes several shaped cut out portions 814 which assist in positioning the elongated member 650. As illustrated in **FIGURE 33**, the cut out portions 814 are sized and configured to engage the surface of elongated member 650 and move the elongated member 650 from an initial location (illustrated in dashed line) to a desired location. In the illustrated embodiment, the cut out portions 814 are semicircular, to match the round elongated member 650. However, other shaped cut out portions may be provided to match other shaped elongated members.

[0239] As illustrated in **FIGURE 34**, the guide apparatus 800 is used in cooperation with the endoscopic screwdriver 660 to attach the cap screw 610. The distal end of the body portion 804 includes a pair of elongated openings 816. The openings 816 provide a window to enable the physician to endoscopically view the cap screw 610 retained at the distal tip 666 of the endoscopic screw driver 660. Fewer or more than two openings can be provided and the openings 816 need not be elongated.

[0240] The guide apparatus 800 and the endoscopic screwdriver 660 cooperate as follows in one application. The guide apparatus 800 is configured to be positioned in a surrounding configuration with the screwdriver 600. In the illustrated embodiment, the body portion 804 is configured for coaxial placement about the screwdriver 660 in order to distribute the contact force of the guide apparatus 800 on the elongated member 650. The distal portion 806 of the guide apparatus 800 may bear down on the elongated member 650 to seat the elongated member 650 in the notches 632 in the housing 604. The "distributed" force of the guide apparatus 800 may contact the elongated member 650 on at least one or more locations. In addition,

the diameter of central bore 808 is selected to be marginally larger than the exterior diameter of cap screw 610, such that the cap screw 610 may freely slide down the central bore 808, while maintaining the orientation shown in **FIGURE 34**. This configuration allows the physician to have effective control of the placement of the cap screw 610 into the housing 604. The cap screw 610 is releasably attached to the endoscopic screwdriver 660 by means of spring member 672 engaged to the interior wall of hexagonal recess 611 as it is inserted within the bore 808 of the body portion 804 of guide apparatus 800. The cap screw 610 is attached to the housing 604 by engaging the threads 615 of the cap screw 610 with the threads 634 of the housing.

[0241] As illustrated in **FIGURE 35**, tightening of the cap screw 610 fixes the assembly of the housing 604 with respect to the elongated member 650. In particular, the distal surface of the cap screw 610 provides a distal force against the elongated member 650, which in turn drives the spacer member 606 against the joint portion 614 of the screw portion 602, which is fixed with respect to the housing 604.

[0242] If locations of the vertebrae are considered acceptable by the physician, then the fixation procedure is substantially complete once the cap screws 610 have been attached to the respective housings 604, and tightened to provide a fixed structure as between the elongated member 650 and the various fasteners 600. However, if compression or distraction of the vertebrae with respect to one another is required additional apparatus would be used to shift the vertebrae prior to final tightening all of the cap screws 610.

[0243] In the illustrated embodiment, this step is performed with a surgical instrument, such as a compressor-distractor instrument 900, illustrated in **FIGURE 36**, which is useful to relatively position bone structures in the cephcaudal direction and to fix their position with respect to one another. Thus, the compressor-distractor instrument 900 has the capability to engage two fasteners 600 and to space them apart while simultaneously tightening one of the fasteners to fix the spacing between the two vertebrae, or other bone structures. Moreover, the compressor-distractor instrument 900 may also be used to move two fasteners 600, and the vertebrae attached thereto into closer approximation and fix the spacing therebetween.

[0244] The distal tool portion 902 of one embodiment of the compressor-distractor instrument 900 is illustrated in **FIGURE 36**. The distal tool portion 902 includes a driver portion 904 and a spacing member 906. The driver portion 904 has a distal end portion 908 with a plurality of wrenching flats configured to engage the recess 611 in the proximal face of the cap screw 610, and to apply torque to the cap screw. The driver portion 904 is rotatable about the longitudinal axis (indicated by arrow M) to rotate the cap screw 610 relative to the fastener 600. Accordingly, the driver portion 904 can be rotated to loosen the cap screw 610 on the fastener 600 and permit movement of the elongated member 650 connected with the vertebra relative to the fastener 600 connected with the vertebra. The cap screw 610 can also be rotated in order to tighten the cap screw 610 and clamp the elongated member 650 to the fastener 600.

[0245] The distal tool portion 902 may also include a spacing member, such as spacing member 906, which engages an adjacent fastener 600b while driver member 904 is engaged with the housing

604a to move the fastener 600b with respect to the fastener 600a. In the exemplary embodiment, spacing member 906 comprises a jaw portion that is pivotably mounted to move between a first position adjacent the driver portion and a second position spaced from the driver portion, as shown in **FIGURE 36**. The distal tip 910 of the spacing member 906 is movable relative to the driver portion 904 in a direction extending transverse to the longitudinal axis. (Further details and features related to compressor-distractor apparatuses are described in U.S. Application No. 10/178,875, filed June 24, 2002, entitled "Surgical Instrument for Moving Vertebrae," published as U.S. Patent Application Publication No. 2003/0236529A1 on Dec. 25, 2003, which is incorporated by reference in its entirety herein. Additionally, further details related to instrumentation for moving a vertebra are described in U.S. Patent No. 6,648,888, issued November 18, 2003; PCT Application No. PCT/US02/28106, filed September 5, 2002, titled SURGICAL INSTRUMENT FOR MOVING VERTEBRAE; PCT Application No. PCT/US03/27879, filed September 5, 2003, titled SURGICAL INSTRUMENT FOR MOVING A VERTEBRAE; and PCT Application No. PCT/US03/04361, filed February 13, 2003, titled APPARATUS FOR CONNECTING A LONGITUDINAL MEMBER TO A BONE PORTION, which are hereby incorporated by reference in their entireties herein.)

[0246] As illustrated in **FIGURE 36**, the spacer member 906 can be opened with respect to the driver portion 904 to space the vertebrae farther apart (as indicated by arrow N). The distal portion 910 of the spacer member 906 engages the housing 604b of fastener 600b and moves fastener 600b further apart from fastener 600a to distract the vertebrae. Where the vertebrae are to be moved closer together, e.g. compressed, the spacer member 906 is closed with respect to the driver portion 904 (arrow P), as illustrated in **FIGURE 37**. The distal portion 910 of the spacer member 906 engages the housing 604b of the fastener 600b and moves the fastener 600b towards the fastener 600a. When the spacing of the vertebrae is acceptable to the physician, the cap screw 610a is tightened by the driver member 904, thereby fixing the relationship of the housing 604a with respect to the elongated member 650, and thereby fixing the position of the vertebrae, or other bone structures, with respect to one another. In one application, once the elongated member 650 is fixed with respect to the fasteners 600, the fixation portion of the procedure is substantially complete.

2. Fusion Systems and Devices

[0247] Although fixation may provide sufficient stabilization, in some cases it is also desirable to provide additional stabilization. For example, where one or more discs has degraded to the point that it needs to be replaced, it may be desirable to position an implant, e.g., a fusion device, a prosthetic disc, a disc nucleus, etc., in the intervertebral space formerly occupied by the disc.

[0248] In one application, a fusion device is inserted between adjacent vertebrae V. Portions of the fusion procedure can be performed before, during, or after portions of the fixation procedure. **FIGURES 38-42** illustrate one embodiment of a fusion device, referred to herein as a spinal implant 2010, that is inserted between adjacent vertebrae. The spinal implant 2010 preferably is placed between adjacent

vertebrae to provide sufficient support to allow fusion of the adjacent vertebrae, as shown in **FIGURES 48-49**. The spinal implants 2010 are preferably made from an allograft material, though other materials could also be used, including autograft, xenograft, or some non-biologic biocompatible material, such as titanium or stainless steel. Also, where non-biologic materials are used, the implant 2010 may be configured as a cage or other suitable configuration.

[0249] The spinal implant 2010 (**FIGURES 38-42**) has a first end 2020 for insertion between adjacent vertebrae V. The first end 2020 has a tapered surface 2022 to facilitate insertion of the implant between adjacent vertebrae V. The surface 2022 defines an angle X of approximately 45° as shown in **FIGURE 41**.

[0250] The spinal implant 2010 (**FIGURES 38-39**) has a second end 2030 that is engageable with a tool 2032 (**FIGURE 51**) for inserting the implant between the adjacent vertebrae V. The tool 2032 has a pair of projections 2034, one of which is shown in **FIGURE 51**, that extend into recesses 2036 and 2038 in the end 2030 of the implant 2010. The recesses 2036 and 2038 (**FIGURES 38-39**) extend from the second end 2030 toward the first end 2020. The recess 2036 (**FIGURE 41**) is defined by an upper surface 2040 and a lower surface 2042 extending generally parallel to the upper surface 2040. The recess 2038 (**FIGURE 39**) has a lower surface 2046 and an upper surface 2048. The upper surface 2048 extends generally parallel to the lower surface 2046.

[0251] The recesses 2036 and 2038 define a gripping portion 2052. The projections 2034 on the tool 2032 extend into the recesses 2036 and 2038 and grip the gripping portion 2052. The projections 2034 engage the upper and lower surfaces 2040 and 2042 of the recess 2036 and the upper and lower surfaces 2046 and 2048 of the recess 2038. Accordingly, the tool 2032 can grip the implant 2010 for inserting the implant between the adjacent vertebrae V.

[0252] As viewed in **FIGURES 38-41**, the implant 2010 has an upper surface 2060 for engaging the upper vertebra V. The implant 2010 has a lower surface 2062, as viewed in **FIGURES 38-41**, for engaging the lower vertebra V. The upper and lower surfaces 2060 and 2062 extend from the first end 2020 to the second end 2030 of the implant 2010 and parallel to the upper and lower surfaces 2040, 2042, 2046, and 2048 of the recesses 2036 and 2038. The upper surface 2060 has teeth 2064 for engaging the upper vertebra V. The lower surface 2062 has teeth 2066 for engaging the lower vertebra V. Although **FIGURES 38-39** show four teeth 2064 and four teeth 2066, it is contemplated that any number of teeth could be used.

[0253] A first side surface 2070 and a second side surface 2072 extend between the upper and lower surfaces 2060 and 2062. The first side surface 2070 extends along a first arc from the first end 2022 of the implant 2010 to the second end 2030. The second side surface 2072 extends along a second arc from the first end 2022 to the second end 2030. The first and second side surfaces 2070 and 2072 are concentric and define portions of concentric circles. The teeth 2064 and 2066 extend parallel to each other

and extend between the side surfaces 2070 and 2072 and along secant lines of the concentric circles defined by the side surfaces.

[0254] The implant 2010 preferably is formed by harvesting allograft material from a femur, as known in the art. The femur is axially cut to form cylindrical pieces of allograft material. The cylindrical pieces are then cut in half to form semi-cylindrical pieces of allograft material. The semi-cylindrical pieces of allograft material are machined into the spinal implants 2010.

[0255] A pair of spinal implants 2010 may be placed bilaterally between the adjacent vertebrae V. The access device 20 is positioned in the patient's body adjacent the vertebrae V. The skirt portion 24 of the access device 20 preferably is in a radially expanded condition to provide a working space adjacent the vertebrae V as described above. Disc material between the vertebrae V can be removed using instruments such as kerrisons, rongeurs, or curettes. A microdebrider may also be utilized to remove the disc material. An osteotome, curettes, and scrapers can be used to prepare end plates of the vertebrae V for fusion. Preferably, an annulus of the disc is left between the vertebrae V.

[0256] Distracters can be used to sequentially distract the disc space until the desired distance between the vertebrae V is achieved. The fusion device or implant 2010 is placed between the vertebrae V using the tool 2032. The first end 2020 of the implant 2010 is inserted first between the vertebrae V. The implant 2010 is pushed between the vertebrae V until the end 2030 of the implant is between the vertebrae. A second spinal implant 2010 is inserted on the ipsilateral side using the same procedure.

[0257] A shield apparatus 3100 with an elongated portion 3102 may be used to facilitate insertion of the implants 2010 between the vertebrae V. A distal portion 3110 of the apparatus 3100 may be placed in an annulotomy. The implant 2010 is inserted with the side surface 2170 facing the elongated portion 3102 so that the apparatus 3100 can act as a "shoe horn" to facilitate or guide insertion of the implants 2010 between the vertebrae.

[0258] The implants 2010 may be inserted between the vertebrae V with the first ends 2020 located adjacent each other and the second ends 2030 spaced apart from each other, as shown in **FIGURE 48**. The implants 2010 may also be inserted between the vertebrae V with the first ends 2020 of the implants 2010 spaced apart approximately the same distance that the second ends 2030 are spaced apart. It is contemplated that the implants 2010 may be inserted in any desired position between the vertebrae V. It is also contemplated that in some embodiments only one implant 2010 may be inserted between the vertebrae V. Furthermore, it is contemplated that the implants 2010 may be inserted between vertebrae using an open procedure.

[0259] Another embodiment of a fusion device or spinal implant 2110 is illustrated in **FIGURES 43-47**. The spinal implant 2110 is substantially similar to the embodiment disclosed in **FIGURES 38-42**. The implant 2110 is placed between the adjacent vertebrae V to provide sufficient support to allow fusion of the adjacent vertebrae, as shown in **FIGURE 50**. The spinal implant 2110 is preferably made from an allograft

material, though the materials described above in connection with the spinal implant 2010 may also be used. Also, as with the implant 2010, the implant 2110 may be formed as a cage or other suitable configuration.

[0260] The spinal implant 2110 (**FIGURES 43-47**) has a first end 2120 for insertion between the adjacent vertebrae V. The first end 2120 has a tapered surface 2122 to facilitate insertion of the implant between the adjacent vertebrae V. The surface 2122 defines an angle Y of approximately 45° as shown in **FIGURE 65**.

[0261] The spinal implant 2110 (**FIGURES 43-44**) has a second end 2130 that is engageable with the projections 2034 on the tool 2032 for inserting the implant between the adjacent vertebrae V. The projections 2034 extend into recesses 2136 and 2138 in the end 2130 of the implant 2110. The recesses 2136 and 2138 extend from the second end 2130 toward the first end 2120. The recess 2136 (**FIGURES 43 and 46**) is defined by an upper surface 2140 and a lower surface 2142 extending generally parallel to the upper surface 2140. The recess 2138 (**FIGURES 44**) has a lower surface 2146 and an upper surface 2148 extending generally parallel to the lower surface 2146.

[0262] The recesses 2136 and 2138 define a gripping portion 2152. The projections 2034 on the tool 2032 extend into the recesses 2136 and 2138 and grip the gripping portion 2152. The projections 2034 engage the upper and lower surfaces 2140 and 2142 of the recess 2136 and the upper and lower surfaces 2146 and 2148 of the recess 2138. Accordingly, the tool 2032 can grip the implant 2110 for inserting the implant between the adjacent vertebrae V.

[0263] As viewed in **FIGURES 43-46**, the implant 2110 has an upper surface 2160 for engaging the upper vertebra V. The implant 2110 has a lower surface 2162, as viewed in **FIGURES 43-46**, for engaging the lower vertebra V. The upper and lower surfaces 2160 and 2162 extend from the first end 2120 to the second end 2130 of the implant 2110 and parallel to the upper and lower surfaces 2140, 2142, 2146, and 2148 of the recesses 2136 and 2138. The upper surface 2160 has teeth 2164 for engaging the upper vertebra V. The lower surface 2162 has teeth 2166 for engaging the lower vertebra V. Although **FIGURE 44** shows four teeth 2164 and four teeth 2166, it is contemplated that any number of teeth could be used.

[0264] A first side surface 2170 and a second side surface 2172 extend between the upper and lower surfaces 2160 and 2162. The first side surface 2170 extends along a first arc from the first end 2122 of the implant 2110 to the second end 2130. The second side surface 2172 extends along a second arc from the first end 2120 to the second end 2130. The first and second side surfaces 2170 and 2172 are concentric and define portions of concentric circles. The teeth 2164 and 2166 extend parallel to each other and between the side surfaces 2170 and 2172 along secant lines of the concentric circles defined by the side surfaces.

[0265] The implant 2110 preferably is formed by harvesting allograft material from a femur, as is known in the art. The femur is axially cut to form cylindrical pieces of allograft material. The cylindrical

pieces are then cut in half to form semi-cylindrical pieces of allograft material. The semi-cylindrical pieces of allograft material are machined into the spinal implants 2110.

[0266] A spinal implant 2110 is placed unilaterally between the adjacent vertebrae V. The access device 20 is positioned in the patient's body adjacent the vertebrae V. The skirt portion 24 of the access device 20 preferably is in a radially expanded condition to provide a working space adjacent the vertebrae V as described above. Disc material between the vertebrae V can be removed using instruments such as kerrisons, rongeurs, or curettes. A microdebrider may also be utilized to remove the disc material. An osteotome, curettes, and scrapers can be used to prepare end plates of the vertebrae V for fusion. Preferably, an annulus of the disc is left between the vertebrae V.

[0267] Distracters are used to sequentially distract the disc space until the desired distance between the vertebrae V is achieved. The implant 2110 is placed between the vertebrae V using the tool 2032. It is contemplated that the apparatus 3100 could be used also. The first end 2120 of the implant 2110 is inserted first between the vertebrae V. The implant 2110 is pushed between the vertebrae V until the end 2130 of the implant is between the vertebrae. It is contemplated that the implant 2110 may be inserted in any desired position between the vertebrae V. It is also contemplated that in some embodiments more than one implant 2110 may be inserted between the vertebrae.

[0268] The apparatus or shield 3100 for use in placing the fusion devices or spinal implants between the vertebrae is illustrated in **FIGURES 52-56**. The apparatus 3100 preferably includes an elongated body portion 3102, which protects the nerve root or dura, and a mounting portion 3104, which allows for the surgeon to releasably mount the apparatus 3100 to the access device 20. Consequently, the surgeon is able to perform the surgical procedures without requiring the surgeon or an assistant to continue to support the apparatus 3100 throughout the procedure, and without reducing the field of view.

[0269] The apparatus 3100 may be manufactured from a biocompatible material such as, for example, stainless steel. In the illustrated embodiment, apparatus 3100 is manufactured from stainless steel having a thickness of about 0.02 inches to about 0.036 inches. The elongated body portion 3102 has dimensions that correspond to the depth in the body in which the procedure is being performed, and to the size of the body structure that is to be shielded by elongated body portion 3102. In the exemplary embodiment, the elongated body portion 3102 has a width 3106 of about 0.346 inches and a length of about 5.06 inches (**FIGURE 53**), although other dimensions would be appropriate for spinal surgical procedures performed at different locations, or for surgical procedures involving different body structures. The distal tip portion 3110 of the apparatus 3100 may have a slightly curved "bell mouth" configuration which allows for atraumatic contact with a body structure, such as a nerve. It is contemplated that the elongated body portion may have any desired shape.

[0270] The mounting portion 3104 preferably allows the apparatus 3100 to be secured to a support structure in any number of ways. In the exemplary embodiment, mounting portion 3104 may include

a ring portion. With reference to **FIGURES 52-56**, ring portion 3120 has a substantially ring-shaped configuration with an opening 3124, which defines an angle 3126 of about 90 degrees of the total circumference of the ring portion 3120. As will be described in greater detail below, the angle 3126 is a nominal value, because the ring portion 3104 is resilient, which permits the opening 3124 to change size during the mounting process.

[0271] In the illustrated embodiment, the mounting portion 3104 has a substantially cylindrical configuration in order to be mounted within the interior lumen of the access device 20, as will be described below. The ring portion 3104 has an exterior dimension 3130 of about 0.79 inches, and an interior dimension 3132 of about 0.76 inches. It is understood that the dimensions of the ring portion 3104 can be different, such as, for example, where the access device 20 has a different interior dimension. Moreover, the cylindrical shape of the ring portion 3104 can change, such as, for example, where the apparatus 3100 is used with a support member having a differently shaped internal lumen.

[0272] Finger grip portions 3122 preferably extend from the mounting portion 3104 and allow the surgeon to apply an inwardly directed force (as indicated by arrows A) to the ring portion 3120. The resilient characteristics of the ring portion 3120 allow the material to deflect thereby reducing the exterior dimension 3130 and reducing the spacing 3124. Releasing the finger grip portions 3122 allows the ring portion to move towards its undeflected condition, thereby engaging the interior wall of the access device 20.

[0273] The elongated body portion 3102 and the mounting portion 3104 may be manufactured from a single component, such as a sheet of stainless steel, and the mounting portion 3104 may be subsequently formed into a substantially cylindrical shape. In another embodiment, the mounting portion 3104 may be manufactured as a separate component and coupled to the elongated body portion, by techniques such as, for example, welding and/or securement by fasteners, such as rivets.

[0274] The access device 20 serves as a stable mounting structure for apparatus 3100. In particular, mounting portion 3104 is releasably mounted to the interior wall of proximal wall portion 22 of access device 20. Elongated body portion 3102 extends distally into the operative site to protect the desired body structure, such as the nerve, as will be described below.

[0275] To install the apparatus 3100 within the interior passage of the proximal wall portion 22, the surgeon may apply an inwardly directed force on the ring portion 3120, thereby causing the ring portion to resiliently deform, as illustrated by dashed line and arrows B in **FIGURE 59**. The surgeon subsequently inserts the apparatus 3100 into the interior lumen of the proximal wall portion 22 (as indicated by arrow C) to the position of ring portion 3104 illustrated in solid line in **FIGURE 58**. When the surgeon releases the finger grip portions 3122, the ring portion 3120 resiliently moves towards its undeflected configuration, thereby engaging the interior lumen of the proximal wall portion 22. Advantages of some embodiments include that the mounting portion 3104 is easily removed and/or moved with respect to the access device 20 without disturbing the position of the access device 20 or any other instrumentation.

[0276] As illustrated in **FIGURE 57**, the configuration of the mounting portion 3104 and the elongated body portion 3102 allow the elongated body portion to occupy a small space along the periphery of the proximal wall portion 3122. This allows the apparatus to protect the desired body structure without blocking access for the insertion of other surgical instrumentation, and without blocking visibility by the surgeon during the procedure.

[0277] The mounting portion 3104 is one exemplary configuration for mounting the apparatus 3100 to the support structure. It is contemplated that the apparatus 3100 may be mounted within the access device 20 in any suitable manner.

[0278] When in position, the distal end portion 3110 covers the exiting nerve root R, while exposing the disc annulus A (See **FIGURE 57**). As discussed above, the debridement and decortication of tissue covering the vertebrae, as well as a facetectomy and/or laminectomy if indicated, are preferably performed prior to the insertion of apparatus 3100 into the surgical space. Accordingly, in some embodiments, there is no need to displace or retract tissue, and apparatus 3100 merely covers the nerve root and does not substantially displace the nerve root or any other body tissue. It is understood that the term "cover" as used herein refers to apparatus 3100 being adjacent to the body structure, or in contact with the body structure without applying significant tension or displacement force to the body structure.

[0279] Additional surgical instrumentation S may be inserted into the access device to perform procedures on the surrounding tissue. For example, an annulotomy may be performed using a long handled knife and kerrisons. A discectomy may be completed by using curettes and rongeurs. Removal of osteophytes which may have accumulated between the vertebrae may be performed using osteotomes and chisels.

[0280] As illustrated in **FIGURE 60**, the elongated body portion 3102 preferably is rotated to protect the spinal cord, or dura D, during the above procedures. The surgeon may change the position of the apparatus 3100 by approximating the finger grips 3122 to release the ring portion from engagement with the inner wall of the proximal wall portion 20, and then re-position the apparatus 3100 without disturbing the access device 20 (as shown in **FIGURE 58**).

[0281] During certain surgical procedures, it may be useful to introduce crushed bone fragments or the fusion devices 2010 or 2110 to promote bone fusion. As illustrated in **FIGURES 61-62**, apparatus 3100 is useful to direct the implants into the space I between adjacent vertebrae V. As shown in the figures, the distal portion 3110 of the elongated body portion 3102 is partially inserted into the space I. The distal end portion 3110, is positioned between adjacent vertebrae V, and creates a partially enclosed space for receiving the implants or other material therein.

[0282] Another embodiment of the apparatus or shield is illustrated in **FIGURES 63-64**, and designated apparatus 3200. Apparatus 3200 is substantially identical to apparatus 3100, described above, with the following differences noted herein. In particular, distal end portion 3210 includes a pair of surfaces

3240 and 3242. Surface 3240 is an extension of elongated shield portion 3202, and surface 3242 extends at an angle with respect to surface 3240. In the exemplary embodiment, surfaces 3240 and 3242 defined an angle of about 90 degrees between them. Alternatively another angle between surfaces 3240 and 3242 may be defined as indicated by the body structures to be protected.

[0283] Distal end portion 3210 allows the apparatus to provide simultaneous shielding of both the dura D and the nerve root R. In **FIGURES 65A-65B**, surface 3242 shields the dura D, and surface 3240 shields the nerve root R. It is understood that surfaces 3240 and 3242 may be interchanged with respect to which tissue they protect during the surgical procedure.

[0284] According to the exemplifying embodiment, once the fusion and fixation portions of the procedure have been performed, the procedure is substantially complete. The surgical instrumentation, such as the endoscope 500 can be withdrawn from the surgical site. The access device 20 is also withdrawn from the site. The muscle and fascia typically close as the access device 20 is withdrawn through the dilated tissues in the reduced profile configuration. The fascia and skin incisions are closed in the typical manner, with sutures, etc. The procedure described above may be repeated for the other lateral side of the same vertebrae, if indicated.

II. FURTHER SPINAL IMPLANTS AND PROCEDURES THAT MAY BE IMPLEMENTED USING THE SYSTEMS DESCRIBED ABOVE

[0285] *paragraph #s? Various embodiments of spinal apparatuses and procedures that are particularly well-suited for implementation using the systems described above are set forth below. These systems are described separately, and in detail; however, it should be understood that this description is only illustrative of the principles of the invention. Various modifications, alterations, and combinations can be made by those skilled in the art without departing from the scope and spirit of the invention. In fact, many of the different spinal implants may advantageously be employed simultaneously to treat certain spinal conditions.

A. Apparatuses, Systems and Methods for Replacing a Spinal Disc and Preserving Motion

[0286] One type of procedure that can be performed by way of the systems and apparatuses described herein involves replacement of one or more of a patient's spinal discs with an implant, e.g., a prosthetic device, that provides the functions of the spinal disc while preserving or restoring a degree of normal motion after recovery. Such a procedure may be applied to a patient suffering degenerative disc disease or otherwise suffering from disc degeneration. A variety of motion preserving implants that may be applied to replace a damaged or degenerating disc are described below. The access devices and systems described herein enable these devices and methods associated therewith to be practiced minimally invasively.

1. Spinal Implant with Articulation Similar to the Knee

[0287] A first type of spinal implant configured to preserve or restore a degree of normal motion after recovery is shown in **FIGURES 66A – 69B**. The first type is characterized by articulating in a manner similar to that of a human knee.

[0288] **FIGURES 66A – 66C** and **67A – 67C** show a first portion 4001 and a second portion 4010 of the implant respectively. In one embodiment, the implant is a kidney-shaped device, as viewed from a top plan view. The implant includes the first portion 4001 and the second portion 4010, both of which are kidney-shaped in one embodiment. The implant may be placed between adjacent vertebrae in a manner similar to the placement of the implant 2110, shown in **FIGURE 50**. Each of the first portion 4001 and second portion 4010 has an anterior end 4040, 4042, an opposing posterior end 4044, 4046, and two lateral sides 4048, 4050 and 4052, 4054.

[0289] The first portion and the second portion articulate with one another to form an artificial disc that operates in a manner similar to a human knee, e.g., as a knee-type joint, that permits limited rotation of the first portion 4001 with respect to the second portion 4010 about a vertical axis X_1. The range of rotation permitted preferably is about 10 degree, e.g., +/-5 degrees off center in either direction. The implant preferably produces a moderate degree of restraint to permit over-rotation.

[0290] The first portion 4001 further comprises a substantially planar, or flat, first superior surface 4002 and an opposing contoured or articulating first inferior surface 4003 comprising two laterally juxtaposed convex portions 4004, 4005 of substantially the same shape. The second portion 4010 further comprises a substantially planar, or flat, second inferior surface 4011 and an opposing contoured or articulating second superior surface 4012 comprising two laterally juxtaposed concave portions 4013, 4014 which are larger in size than the respective convex portions of the first portion 4001.

[0291] The first and second portions 4001, 4010 can be described by the frontal (or transverse) and median (or sagittal) sections of their respective articulating surfaces. The articulating first inferior surface 4003 of the first portion 4001 has a sagittal section, in the anterior to posterior direction along plane P_1, resembling an outwardly curved arch, e.g., convex, having a varying radius of curvature. The condyles 4004, 4005 can each have a sagittal section, along the midpoint of each condyle (see the planes P_4 and P_5, respectively), resembling a curve comprising at least a portion having a varying radius of curvature. In one embodiment, the shape of the curve in the sagittal section will approximate the shape of a curve described by a Fibonacci mathematical series.

[0292] The condyles 4004, 4005 can have a combined transverse section, in a lateral to lateral direction along plane P_2, resembling a bimodal outwardly curved arch, e.g., two convex curves, having a varying radius of curvature. The plane P_2 is disposed approximately half way between the anterior end 4040 and the posterior end 4044. The condyles 4004, 4005 can each have an individual transverse section, along the plane P_2, resembling a curve comprising at least a portion having a varying radius of curvature. In a

preferred embodiment, the shape of the curve of the transverse section for each condyle 4004, 4005 will approximate the shape of a curve described by a Fibonacci mathematical series.

[0293] The articulating second superior surface 4012 of the second portion 4010 has a sagittal section, in an anterior to posterior direction along plane P_{10}, resembling an inwardly curved arch, e.g., concave, having a varying radius of curvature. The modes 4013, 4014 can each have a sagittal section, along the midpoint of each mode (see the planes P_{13} and P_{14}, respectively), resembling a curve comprising at least a portion having a varying radius of curvature. In a preferred embodiment, the shape of the concave curves in the sagittal section will approximate the shape of a curve described by a Fibonacci mathematical series.

[0294] The concave modes 4013, 4014 can have a combined transverse section, in a lateral to lateral direction along plane P_{11}, resembling a bimodal inwardly curved arch, e.g. two concave curves. The plane P_{11} is disposed approximately half way between the anterior end 4042 and the posterior end 4046. The concave modes 4013, 4014 can each have an individual transverse section, along plane P_{11}, resembling a curve comprising at least a portion having a varying radius of curvature. In a preferred embodiment, the shape of the curve of the transverse section for each concave mode 4013, 4014 will approximate the shape of a curve described by a Fibonacci mathematical series.

[0295] The respective shapes of the concave and convex portions of the articulating surfaces 4003, 4012, respectively, will comprise portions that are substantially complementary; however, the articulating surfaces will be shaped to permit articulation of the first and second portions 4001, 4010 in a manner resembling the articulation of a human knee. Thus, the articulating surfaces 4003, 4012 can be regularly or irregularly shaped as at least partially complementary portions of spheroids, paraboloids, hyperboloids or ellipsoids of revolution or combinations thereof As discussed above, the concave and convex portions of the articulating surfaces can be described by both coronal, i.e., transverse, and sagittal arcs which are variable, i.e., have varying radii of curvature, and allow for changing instant centers of rotation and moderate degrees of rotation during articulation of the surfaces 4003, 4012.

[0296] The articulating surfaces 4003 and 4012 are designed so that the respective concave and convex portions thereof comprise a major portion of substantially the entirety of the respective articulating surfaces 4003 and 4012. Thus, while the articulating surfaces are surrounded by respective surfaces defining the outer periphery of each of the respective portions 4001 and 4010, the articulating surfaces 4003 and 4012 do not have respective inferior and superior surface portions that completely surround the articulating respective portions of said surfaces. For example, substantially all of the convex-shaped portions 4004, 4005 of the articulating surface 4003 can articulate with substantially all of the cave-shaped portions 4013, 4014 of the articulating surface 4012.

[0297] **FIGURES 68A** and **68B** depict one embodiment of a spinal implant 4020 that includes a superior first portion 4021 and an inferior second portion 4022. The first portion 4021 includes a first

articular surface 4025 which articulates with a second articular surface 4026 of the second portion 4022. **FIGURE 68A** is a side elevation view of the implant 4020 and it corresponds to a lateral view thereof. As the first and second portion 4021, 4022 articulate along their articulating surfaces 4025 and 4026, respectively, the first portion 4021 will move in the direction indicated by the arrow (B) from the home position depicted in **FIGURE 68A** to a second position depicted in **FIGURE 68B**. In the home position, the first and second portions 4021, 4022 share a common center of rotation 4023a, 4023b. However, when the first portion 4021 is articulated to a second position as depicted in **FIGURE 68B**, the instant centers of rotation 4023a, 4023b are no longer coincident. Therefore, when a patient using this embodiment bends in a forward or backward manner, i.e., flexes in an anteroposterior fashion, the instant centers of rotation 4023a, 4023b will be displaced away from each other in an anteroposterior fashion, i.e., there will be an anteroposterior translation of the instant center of rotation 4023b with respect to the instant center of rotation 4023a.

[0298] **FIGURES 69A** and **69B** depict partial cross-sectional rear, or posterior, elevation views of another embodiment of an spinal implant 4030 comprising a first superior portion 4031 and a second inferior portion 4032. The first superior portion 4031 comprises a bicondylar articulating surface which articulates with a bimodal concave articulating surface 4034 of the second portion 4032. The first and second portions 4031, 4032 are depicted in a home or neutral position. When the first portion 4031 is translated laterally along the arrow (T) with respect to the second portion 4032, the first portion 4031 will tilt slightly with respect to the second portion 4032 and the instant centers of rotation 4035a, 4035b will be displaced from one another. Therefore, in one embodiment, the spinal implant will comprise first and second articulating surfaces which are adapted to provide a changing center of rotation when the articulating surfaces are translated or articulated with respect to one another in a lateral-to-lateral fashion.

[0299] Although not shown, in one embodiment, one or both of the first and second portions of any of the implants 4020, 4030 may include fasteners to facilitate their attachment to adjacent vertebrae. These fasteners may comprise one or more projections on one of the generally planar surfaces of the first and /or second portions. In one embodiment, two projections are provided that mate with corresponding cavities in adjacent vertebrae. Alternatively or additionally, multiple screw holes may be disposed in the first or second portions 4001, 4010 through which cancellous screws may be inserted and screwed into the adjacent vertebra. The fasteners may comprise other known means for providing attachment to a selected portion of the vertebra, including screws, nails, hooks, rivets, adhesives, wires, bands and straps. In one embodiment, the planar surfaces 4002, 4011 can further comprise porous coatings to enhance ossification thereof, such as by promoting the ingrowth of bone.

[0300] Further details of the first type of implant may be found in U.S. Patent No. 6,039,763, issued March 21, 2000, which is hereby incorporated by reference in its entirety.

[0301] Further details of similar structures that replace spinal discs with prosthetic devices may be found in U.S. Patent No. 5,314,477, issued May 24, 1994, U.S. Patent No. 5,562,738, issued October

8, 1996, U.S. Patent No. 5,676,701, issued October 14, 1997, U.S. Patent No. 5,782,832, issued July 21, 1998, U.S. Patent No. 6,156,067, issued December 5, 2000, U.S. Patent No. 6,540,785, issued April 1, 2003, and U.S. Patent No. 6,039,763 assigned to Disc Replacement Technologies, Inc., which are hereby incorporated by reference in their entirety.

2. Spinal Implant with an Internal Pivot

[0302] **FIGURES 70A – 72** show another embodiment of an implant 4110 configured to preserve or restore a degree of normal motion after recovery. The implant 4110 comprises a first element 4120 and a second element 4122. The first element 4120 is coupled to the second element 4122 by an internal pivot 4124 or other suitable means for allowing internal articulation, or relative pivotal movement between the first and second elements 4120, 4122.

[0303] The first element 4120 of the implant 4110 comprises a first fusion chamber 4130, for engaging a first vertebra, e.g., a vertebra located directly superiorly of the first fusion chamber 4130. At least one opening 4132 is formed in the first fusion chamber 4130, to facilitate bone growth into, through, and around the first fusion chamber 4130 from the first vertebra, to fuse the first element to the first vertebra. Preferably, a plurality of openings 4132 are provided to further promote bone ingrowth. Fusion by bone ingrowth provides a generally rigid connection between the implant 4110 and the skeletal structure. Other connection means known in the art could be provided in other embodiments.

[0304] Similarly, the second element 4122 of the implant 4110 comprises a second fusion chamber 4134, substantially similar in construction to the above-described first fusion chamber 4130, and comprising at least one opening 4136 formed therein for facilitating bone growth into, through and around the second fusion chamber 4134 from a second vertebra located directly inferiorly of the second element 4122. Other second connection means may also be provided, as desired, e.g., an adhesive connection, screw connection, pin connection, or any other effective alternative connection means. The second fusion chamber 4134 provides a permanent and secure coupling, as discussed above. The first and second elements 4120, 4122 can be fabricated from biocompatible materials including, without limitation, titanium, surgical alloys, stainless steel, chrome-molybdenum alloy, cobalt chromium alloy, zirconium oxide ceramic, nonabsorbable polymers and other anticipated biocompatible metallic or polymeric materials.

[0305] The internal pivot 4124 of the present invention preferably comprises a first articulation surface 4140 provided on the first element 4120, and an abutting second articulation surface 4142 provided on the second element 4122. The first and second articulation surfaces 4140, 4142 preferably are fabricated from or coated with low-friction, wear and impact-resistant, biocompatible materials, such as, for example, titanium, stainless steel, surgical alloys, chrome molybdenum alloys, cobalt chromium alloy, zirconium oxide ceramic, non-absorbable polymers and other biocompatible metallic or polymeric materials. The internal pivot 4124 resists axial compression between the first and second elements 4120, 4122, but allows relative pivotal movement therebetween. Thus, when implanted, the internal pivot 4124 resists axial compression between first and second vertebra along a support axis extending generally along the spinal column, but permits

pivotal movement between vertebrae. The term "pivotal," is intended to comprehend either or both of a rotational or twisting motion about the support axis (for example, rotation between cervical vertebrae by turning the head to the right or left), and/or a tilting motion angularly inclined in any direction relative to the support axis (for example, nodding the head forward or backward and/or tilting the head downward to the right or left).

[0306] Axial compression, as well as lateral translation normal to the support axis, is resisted between the first and second vertebra by providing the first internal articulation surface 4140 with a void, such as a concave surface 4146, which receives a protuberance, such as a convex surface 4148, projecting from the second internal articulation surface 4142, e.g., like a "ball-and-socket" arrangement. This arrangement allows relative rotation about the support axis between the first and second vertebra. The internal pivot 4124 can be provided with one or more stops to limit the range of rotational movement allowed.

[0307] The internal pivot 4124 preferably further comprises one or more angularly offset bevels 4150 formed in the first internal articulation surface 4140 and/or the second internal articulation surface 4142, to allow relative tilting movement in one or more directions between the adjacent vertebrae defining the interbody space into which the implant 4110 is implanted. In the illustrated embodiment, the first and second internal articulation surfaces 4140, 4142 are each provided with an angularly offset bevel 4150, in a generally pyramidal configuration, thereby enabling tilting movement in all directions (360 degrees). A generally conical configuration is also possible and, likewise, would permit both rotational movement and 360 degree tilting movement.

[0308] The natural range of motion of the spine may be approximated by providing bevels 4150 of approximately 5 degrees around the periphery of each of the first and second articulation surfaces 4140, 4142, thereby allowing approximately 10 degrees of tilt in all directions between adjacent vertebrae. The pivot point or axis of the internal pivot 4124 is generally centrally located on the first and second articulation surfaces 4140, 4142, and may be aligned with the spine's normal axis of rotation when implanted. This location, however, can be selectively varied to position the center of rotation of the internal pivot 4124 centrally, anteriorly, posteriorly, to the left, to the right, or eccentrically (off-center in both the anterior/posterior direction and the left/right direction) of the spine's normal axis of rotation, in order to achieve proper alignment of the spine, thereby restoring optimal sagittal and coronal spinal balance and alignment.

[0309] In one embodiment, the first and second elements 4120, 4122 of the implant 4110 preferably comprise generally hemicylindrical outer walls 4160, 4170 adjoining to form a generally cylindrical body. When in their assembled configuration, the first element 4120 and the second element 4122 abut one another with their respective first and second articulating surfaces 4140, 4142 adjacent and engaging one another, as described above. The first element 4120 preferably further comprises a first radiused outer wall 4160. The one or more openings 4132 for facilitating bone ingrowth are provided in this first radiused outer wall 4160, and communicate with a first fusion chamber 4162 formed between the first radiused outer wall

4160 and the first articulating surface 4140. Similarly, the second element 4122 preferably comprises a second radiused outer wall 4170, defining one or more openings 4136 for facilitating bone ingrowth. The openings 4136 communicate with a second fusion chamber 4172 formed between the second radiused outer wall 4170 and the second articulating surface 4134. The first and second radiused outer walls 4160, 4170 can be provided with threads 4180 to facilitate advancing the implant 4110 into the interbody space during implantation and to help secure the implant 4110 in position once implanted. The threads 4180 on each of the first and second radiused outer walls 4160, 4170 are preferably aligned to form continuous threads when the first and second elements 4120, 4122 are engaged. In some instances, it may be desirable to provide self-tapping threads 4180, and/or to configure the threads 80 to direct bone fragment generated by implantation into the openings 4132. In other embodiments, the threads 80 are replaced with a contoured outer surface comprising smooth, splined, flanged, spiked or beaded surface features. The implant 4110 can further comprise one or more support flanges 4185 in the first and/or second elements 4120, 4122, for additional strength.

[0310] The implant 4110 may further comprise one or more structures to temporarily rigidly coupling the first element 4120 to the second element 4122 to prevent relative movement therebetween. For example, it is preferred that the first and second elements 4120, 4122 be held rigidly in place during installation of the implant 4110 into the interbody space. In addition, the first and second elements 4120, 4122 should remain rigidly coupled for a sufficient length of time after implantation to permit sufficient bone ingrowth into the fusion chambers to prevent relative motion between the implant 4110 and the vertebrae during normal activities of the patient. This temporary stabilization of the first and second elements is accomplished without the requirement of a second surgical procedure through the use of medium-term structures formed from bioreabsorbable material. Examples of bioreabsorbable materials include polyglycolate polymers or analogues, lactides, polydioxanone, polyglyconate, lactide/glycolide copolymers. By appropriate selection of the material(s) of construction, the length of time required to biodegrade the stabilizing means can be effectively controlled. After the stabilizing means are dissolved and absorbed by the body, the first and second elements of the implant 4110 are uncoupled, allowing articulation. **FIGURE 72** shows one structure that includes one or more biodegradable shims 4182 wedged between the first element 4120 and the second element 4122, to prevent relative motion therebetween.

[0311] In another example embodiment, the first and second elements 4120, 4122 are placed in their coupled configuration, as shown in **FIGURES 71-72**, with the spaces between the articulating surfaces 4140, 4142 then being injected or filled with a biodegradable polymer, which provides the medium term temporary stabilizing means to couple the elements in position. Care will be taken to avoid filling the fusion chambers 4130, 4134 and the openings 4132, 4136 to the fusion chambers with the polymer, which could inhibit bone ingrowth. The threads 4180 will also remain exposed to assist in implantation of the device.

[0312] **FIGURE 71** shows a removable and/or bioreabsorbable endcap 4190, which releasably engages a tailing end 4192 of the implant 4110 to couple the first and second elements 4120, 4122. The endcap 4190 can comprise one or more clips 4194 for engaging the implant 4110, and one or more keyways 4196 for engaging a wrench, driver or other actuation device used to advance the implant 4110 into the intervertebral space. A second removable and/or absorbable endcap can be installed on the leading end 4193 of the implant 4110. The endcaps may additionally function to retain the bone fragments within the chambers 4162, 4172 of the fusion chambers 4130, 4134.

[0313] Further details of the second type of motion preserving or restoring implant may be found in U.S. Patent No. 6,440,168, issued August 27, 2002, which is hereby incorporated by reference in its entirety.

[0314] Further details of implants that function similarly to implant 4110 may be found in U.S. Patent No. 6,419,706, issued July 16, 2002, which is hereby incorporated by reference in its entirety.

3. Spinal Implant Arranged for Adequate Deformation

[0315] **FIGURE 73** shows another type of implant configured to preserve or restore a degree of normal motion after recovery. In particular, an implant 4210 includes a plurality of slits 4212 defined in the perimeter surface 4215. The slits 4212 specifically weaken the implant 4210 to enable the implant 4210 to deform as needed. The slits 4212 preferably terminate in perimeter openings 4214, which are larger than the slit thickness. The dimension of the slits 4212, e.g., their placement and anterior-posterior depths and thickness, may be varied. Varying the dimensions or numbers of slits 4212 changes the flexibility of the implant 4210.

[0316] **FIGURE 73** shows that the slits 4212 are substantially at a right angle to an axis (4219) of the implant 4210. In other embodiments a slit may be defined on the perimeter surface 4215 transverse to the axis. However, since the upper and lower surfaces of the implant 4210 do not have to be parallel, the slits 4212 do not have to be parallel with respect to the upper and lower surfaces or with respect to other slits. The number, thickness and depth of the slits may be varied to achieve the level of flexibility desired for the disc prosthesis. Thicker, deeper, or a greater number of slits will increase flexibility. The upper surface and the lower surface of the implant 4210 are shown as being substantially flat. However, there are many surface types that could be used, e.g., surfaces configured to foster bone ingrowth. Preferably, the implant comprises a coating on at least one surface to promote bone ingrowth. This coating may includes ceramic beads, wire meshes, and other types of ceramics.

[0317] The slits 4212 preferably terminate at perimeter openings 4214, or holes. The dimensions of the perimeter openings 4214 may be varied to reduce stress and to change the flexibility of the implant. The geometry of the perimeter openings can be circular or non-circular. The perimeter openings are circular in one embodiment.

[0318] Further details of structures that replace spinal discs with prosthetic devices may be found in U.S. Patent No. 6,579,321, issued June 17, 2003, which is hereby incorporated by reference in its entirety.

[0319] Further details of implants that function similarly to implant 4210 may be found in U.S. Patent No. 6,315,797, issued November 13, 2001, which is hereby incorporated by reference in its entirety.

4. Spinal Implant with a Bone Growth Promoting End Plate and a Cushioning Member

[0320] **FIGURE 74** is a side view of one embodiment of another type of spinal implant 4300. The implant 4300 includes a cushioning member 4302 that is disposed between a pair of endplates 4304. In one embodiment, a plurality of protrusions 4306, e.g., spikes, extend from at least one of the endplates 4304 to help hold the implant 4300 in the interbody space between the adjacent vertebrae. The cushioning member 4302 is configured to cyclically compress and expand in a manner similar to the disc material being replaced and is composed of a suitable material, e.g., polymeric urethane or other suitable elastomers, or other filling material to impart an appropriate level of compressibility. The superior and inferior surfaces of the end plates 4304 may be convex, and may further include grooves, spikes, or other protrusions to maintain the body within the interbody space, as discussed above. The implant 4300 also may be wedge-shaped to help restore or maintain lordosis, particularly if the prosthesis is introduced into the cervical or lumbar regions of the spine. The endplates 4304 of the implant 4300 preferably are formed of metal and/or otherwise provide bone-ingrowth surfaces. Further details of the implant 4300 may be found in U.S. Patent Application Publication No. US 2003/0074076, published April 17, 2003, which is the publication of U.S. Application Serial No. 10/303,385, filed November 25, 2002, which is hereby incorporated by reference in its entirety.

[0321] Further details of implants that function similarly to implant 4300 may be found in U.S. Patent No. 4,911,718, issued March 27, 1990, U.S. Patent No. 4,932,969, issued June 12, 1990, U.S. Patent No. 5,370,697, issued December 6, 1994, U.S. Patent No. 5,556,431, issued September 17, 1996, U.S. Patent No. 6,348,071, issued February 19, 2002, U.S. Patent No. 6,368,350, issued April 9, 2002, U.S. Patent No. 6,582,466, issued June 24, 2003, U.S. Patent No. 6,592,624, issued July 15, 2003, and U.S. Patent Application Publication No. US 2002/0082701, published June 27, 2002, which is the publication of U.S. Application Serial No. 10/085872, filed February 28, 2002, which are hereby incorporated by reference in their entirety.

5. Motion Preserving Spinal Implant

[0322] Another type of spinal implant that can be delivered by way of the access device 20 and which is configured to preserve or restore a degree of motion. **FIGURE 75** shows a spinal implant 4400 that has a pair of opposing members 4402, 4404 for seating against opposing vertebral bone surfaces. The members 4402, 4404 are separated by a spring mechanism. In one embodiment, the spring mechanism includes at least one spirally slotted belleville washer 4406 having radially extending grooves. One of the members 4402, 4404 has a centrally located ball-shaped protrusion 4408 that is rotatably coupled in a central socket in the narrow end of the belleville washer 4406. The wide end of the belleville washer 4406 is held

against the member 4402 by a shield 4410 with rivets 4412. This arrangement prevents the implant 4400 from becoming disassembled under tension loads applied to the members 4402, 4404. The location of the ball joint provides the implant 4400 with a centroid of motion that is centrally located between the vertebral bone surfaces when applied. Thus, the implant 4400 behaves similarly to a healthy natural intervertebral disc.

[0323] Further details of other embodiments related to the implant 4400 are disclosed in U.S. Patent Application Publication No. 2003/0069643, published April 10, 2003, which is the publication of U.S. Application serial No. 10/151,280, filed on May 20, 2002 and U.S. Patent Application Publication No. 2003/0078667, published July 15, 2003, which is the publication of U.S. Application Serial No. 10/324,200, filed December 20, 2002, which are hereby incorporated by reference in their entirety.

6. Further Methods of Applying an Interbody Implant

[0324] **FIGURES 76-79** more particularly illustrate methods whereby an implant 4500 is delivered through an access device 4504 and implanted in an interbody space I defined between a first vertebra V_1 and a second vertebra V_2. The implant 4500 may be any suitable implant, e.g., any of the implants 4020, 4030, 4110, 4210, 4300, 4400. Some methods of implanting the implant 4500 may be similar to the methods of implanting the fusion implant 2010 described above in connection with **FIGURE 51**.

[0325] In one method, access to the interbody space I is provided by inserting the access device 4504 into the patient. The access device 4504 may be configured in a manner similar to the expandable conduit 20 and may be inserted in a similar manner, e.g., over a dilator. The access device 4504 preferably has an elongate body 4508 that has a proximal end 4512 and a distal end 4516. In one embodiment, the elongate body 4508 comprises a proximal portion 4520 and a distal portion 4524. The proximal portion 4520 may have a generally oblong or oval shape (as shown in **FIGURE 76A**), a generally circular shape (as shown in **FIGURE 76B**), or any other suitable shape. The distal portion 4524 preferably is expandable, as discussed above in connection with the expandable conduit 20, to the configuration illustrated in **FIGURES 76, 77,** and **78**. At least one passage 4528 extends through the elongate body 4508 between the proximal end 4512 and the distal end 4516.

[0326] The elongate body 4508 has a length between the proximal end 4512 and the distal end 4516 that is selected such that when the access device 4504 is applied to a patient during a surgical procedure, the distal end 4516 can be positioned inside the patient adjacent a spinal location, and, when so applied, the proximal end 4512 preferably is located outside the patient at a suitable height. As discussed below, various methods can be performed through the access device 4504 by way of a variety of anatomical approaches, e.g., anterior, lateral, transforaminal, postero-lateral, and posterior approaches. The access device 4504 may be used for any of these approaches and may be particularly configured for any one of or for more than one of these approaches. For example, the access device 4504 may be generally lengthened for certain approaches, e.g., lateral and anterior, compared to other approaches, e.g., posterior and postero-lateral. The access device 4504 may be lengthened by lengthening the proximal portion 4520, the distal portion 4524, or the proximal and distal portions 4520, 4524.

[0327] **FIGURE 78** shows that the access device 4504 is configured to be coupled with a viewing element 4532 in one embodiment. The distal portion 4524 of the access device 4504 has an aperture 4536 into which the viewing element 4532 can be inserted, such that a proximal portion of the viewing element 4532 lies external to the proximal portion 4520 and a distal portion of the viewing element 4532 lies within the distal portion 4524 of the access device 4504. In another embodiment, the viewing element 4532 may extend within the access device 4504 substantially entirely the length of the passage 4528. In other embodiments, the viewing element 4532 may be moved to the surgical location entirely externally to the access device 4504. The viewing element 4532 may be configured to be removed from the access device 4504 during the procedure, as required.

[0328] The viewing element 4532 may be any suitable viewing element, such as an endoscope, a camera, loupes, a microscope, a lighting element, or a combination of the foregoing. The viewing element may be an endoscope, such as the endoscope 500, and a camera, which capture images to be displayed on a monitor, as discussed above. Further details of the access device 4504 are set forth in an application entitled MINIMALLY INVASIVE ACCESS DEVICE AND METHOD, filed October 2, 2003, U.S. Application Serial No. 10/678,744, which is hereby incorporated by reference in its entirety.

[0329] In the illustrated methods, the distal end 4516 of the access device 4504 is inserted laterally, as indicated by an arrow 4540, to a surgical location adjacent to at least one vertebra and preferably adjacent to two vertebrae, e.g., the first vertebra V_1 and the second vertebra V_2, to provide access to at least a portion of the interbody space I. In another method, the access device 4504 is inserted postero-laterally, as indicated by an arrow 4544 and the dashed-line outline of the access device 4504 in **FIGURE 76**, to provide access to at least a portion of the interbody space I. As discussed above, the access device 4504 can have a first configuration for insertion to the surgical location over the interbody space I and a second configuration wherein increased access is provided to the interbody space I. **FIGURES 76** and **77** show that the second configuration may provide a cross-sectional area at the distal end 4516 that is larger than that of the first configuration at the distal end 4516. The distal portion 4524 of the access device 4504 may be expanded from the first configuration to the second configuration, as discussed above in connection with the skirt portion 24, using the expander apparatus 200. When so expanded, the distal portion 4524, at the distal end 4516, defines a surgical space 4542 that includes a portion of the interbody space I, e.g., a portion of the external surface of an annulus A.

[0330] As discussed above, in one embodiment, the access device 4504 has a substantially circular cross-sectional shape (as shown in **FIGURE 76B**) in the proximal portion 4520. The access device 4504 may further have a circular cross-section near the proximal end 4512, near the distal end 4516, at the proximal and distal ends 4512, 4516, and from the proximal end 4512 to the distal end 4516. As discussed above, in another embodiment, the access device 4504 has an oblong cross-sectional shape (as shown in **FIGURE 76A**) in the proximal portion 4520. In particular, the access device 4504 may have an oblong cross-

section near the proximal end 4512, near the distal end 4516, at the proximal and distal ends 4512, 4516, and from the proximal end 4512 to the distal end 4516.

[0331] In some methods of applying the implant 4500, a second access device, such as an expandable conduit 20 or other suitable access device, may be inserted into the patient. For example, a second access device could be inserted through a lateral approach on the opposite side of the spine, as indicated by an arrow 4548, to provide access to at least a portion of an interbody space, e.g., the interbody space I. In another embodiment, a second access device could be inserted through a postero-lateral approach on the opposite side of the spine, as indicated by an arrow 4552, to provide access to at least a portion of an interbody space, e.g., the interbody space I. This second access device may provide access to the interbody space I at about the same time as the first access device 4504 or during a later or earlier portion of a procedure. In one method, the implant 4500 is inserted from both sides of the spine using first and second access devices.

[0332] In various applications, one or more implants 4500 may be delivered through one or more access devices, such as the access device 4504, from different directions. For example, a first implant 4500 could be delivered through a first access device from the approach indicated by the arrow 4540, and a second implant 4500 could be delivered through a second access device from the approach indicated by the arrow 4548. In another method, a first implant 4500 could be delivered through a first access device from the approach indicated by the arrow 4540, and a second implant 4500 could be delivered through a second access device from the approach indicated by the arrow 4552. In another method, a first portion of a first implant 4500, e.g., a portion to be coupled with the superior vertebra defining the interbody space I, could be delivered through a first access device from the approach indicated by the arrow 4540, and a second portion of the first implant 4500, e.g., a portion to be coupled with the inferior vertebra defining the interbody space I, could be delivered through a second access device from the approach indicated by the arrow 4548. Thus, any combination of single, multiple implants, or implant sub-components may be delivered through one or more access devices from any combination of one or more approaches, such as the approaches indicated by the arrows 4540, 4544, 4548, 4552, or any other suitable approach.

[0333] **FIGURE 77** shows a lateral view of a portion of a spine of a patient with the access device 4504 delivered thereto. In this figure, the patient's natural disc in the interbody space I has not yet been treated. The access device 4504 is shown in the expanded configuration wherein the perimeter of the distal end 4516 extends outwardly beyond a projection of the perimeter of the proximal end 4512. In one embodiment, the access device 4504 is configured so that when in the expanded configuration, the distal end 4516 does not extend beyond the locations of a nerve root 4572 or the spinal cord. The nerve root 4572 and the spinal cord are located outside the surgical space 4542 defined generally within the perimeter of the distal end 4516 in some embodiments, and therefore are shielded from any implement or implant delivered to the surgical location through the access device 4504. When in position, in addition to providing access to the

interbody space I and the disc material therein, the distal portion 4524 may cover the nerve root 4572 and spinal cord and thereby protect the nerve root 4572 and spinal cord. It is understood that the term "cover" as used in this context refers to distal end 4516 of the access device 4504 being located between the surgical space 4542 and the nerve root 4572 or the spinal cord, or in contact with the nerve root 4572 or the spinal cord without applying significant force, e.g., tension or displacement force, to the nerve root 4572 or the spinal cord. The access device 4504 can provide the additional advantage of gently retracting the nerve root 4572 or other delicate anatomical structures where desirable. Gentle retraction of the nerve root 4572 may be desirable in connection with some approaches, e.g., the lateral approach.

[0334] As discussed above, in some methods, suitable procedures may be performed to prepare the interbody space I to receive an implant, e.g., the implant 4500. For example, degraded natural disc material may be removed in a suitable manner, e.g., a discectomy may be performed. Also, the surfaces of the vertebrae V_1, V_2 facing the interbody space I may be prepared as needed, e.g., the surfaces may be scraped or scored, and/or holes may be formed in the vertebrae V_1, V_2 to receive one or more features formed on a surface of the implant 4500. **FIGURE 77** shows a surgical space 4542 wherein an annulotomy and/or end plate removal may be performed through the access device 4504. Such procedures may necessitate the deployment of additional surgical tools through the access device 4504. For example, an annulotomy may be performed using a long handled knife and kerrisons. A discectomy may be completed by using curettes and rongeurs.

Some procedures may be performed more efficiently with a steerable instrument, e.g., a steerable rongeur or a steerable blade. One type of steerable instrument is described below in connection with FIGURES 116-118. As disclosed in connection with FIGURES 116-118, the steerable instrument is elongated so that a working end (e.g., a rotary cutter assembly or shaver assembly) can be inserted to the spine through any of the access devices described herein, e.g., through the access device 4504. In one technique, when so inserted the steerable instrument of FIGURES 116-118 can be advanced to a disc (e.g., an intervertebral disc) and into the interbody space I where it can cut tissue into relatively small portions or pieces, enabling them to be removed from the interbody space I or a disc space. In some procedures, the steerable instrument of FIGURES 116-118 is used to remove annulus material. In some procedures, the steerable instrument of FIGURES 116-118 is used to remove disc material. In some procedures, the steerable instrument of FIGURES 116-118 is used to remove disc and annulus material. Because of the advantages provided by use of steerable instruments with access devices, various embodiments of these apparatuses may advantageously be combined into a system or a kit.

As discussed more fully below, in some embodiments, the steerable instruments advantageously enable a surgeon to operate on tissue that is not substantially in-line with the longitudinal axis of the access device 4504. In some embodiments, the steerable instruments enable a surgeon to operate on tissue located outside of a projection of the proximal end 4512 of the access device 4504. The steerable instruments also

can act on tissue that is substantially directly in-line with the longitudinal axis and/or within a projection of the proximal end 4512. Additionally, in some embodiments, a steerable instrument can be configured to act on tissue in a region that is outside of the projection of the distal end of the access device when the access device is expanded. Stated another way, the working end of the steerable instrument may be articulated so that the working end is a greater distance from the longitudinal axis of the access device than is the distal end of the access device adjacent to the steerable instrument. This greatly increases the operational range of the surgeon without increasing the amount of tissue retracted between the skin and the spine. Another benefit of the steerable instruments described herein is to enable the surgeon to cut and otherwise act on tissue in a generally longitudinal direction and in a generally lateral direction without requiring lateral movement of the proximal portion of the instrument. This may be achieved by enabling the working end to sweep through a desired range of motion. The range of motion required may be based at least in part on the approach (e.g., for posterolateral, lateral, or any other suitable approach). The use of steerable instruments can greatly increase the efficiency of a procedure and shorten the procedure time.

As discussed more fully below, steerable instruments, such as the steerable instrument of FIGURES 116-118 can be configured so that the working end is articulated from a location at or adjacent to the proximal end of the instrument. This arrangement advantageously locates the means for articulating the steerable instrument outside the body, e.g., proximal of the proximal end 4512 of the access device 4504, when used through the access device 4504. Thus, a surgeon can easily manually manipulate the steerable instrument.

Other tools can be included that enable other procedures to be performed. For example, removal of osteophytes which may have accumulated between the vertebrae may be performed using osteotomes and chisels. All or only a portion of the disc material within the interbody space I may be removed prior to insertion of the implant 4500. In some methods, the disc material is entirely removed where it will serve no further purpose or will detract from the performance of the implant 4500. Any of the foregoing procedures to prepare the interbody space I may be performed though the access device 4504 inserted as shown or through a second access device inserted through any suitable approach.

[0335] In some methods, a distraction means (not shown in **FIGURE 77**) may be provided to further prepare the interbody space I. As indicated by **FIGURE 78**, the distraction means may be used to create a distracted space 4556 in the interbody space I through the same access device used to deliver the implant 4500. The distraction means may take any suitable form, e.g., a paddle distractor, a jacking instrument, etc. Other distraction means known to those of skill in the art could also be used, if configured to be inserted through the access device 4504.

[0336] The distracted space 4556 may be formed by manipulating the distraction means to provide a selected separation between the first vertebra V_1 and the second vertebra V_2. The separation and the amount of disc material removed may be selected based on the size of the implant 4500 so as to create

sufficient space for the implant 4500 to be received therein. After the distracted space 4556 is formed, the distraction means may be removed to free up the passage 4528 to receive the implant 4500.

[0337] In another method, the distraction means is provided through a second access device at about the same time or before the implant 4500 is inserted through the first access device 4504. Any of the approaches described herein or any other suitable approach may be used to deliver the distraction means separately from the implant 4500. In another embodiment, the distraction means is provided through an aperture similar to the aperture 4536 so that the proximal portion of the passage 4528 is unobstructed, and the space therein can be substantially entirely used for the delivery of the implant 4500 during a portion of the method.

[0338] **FIGURE 78** illustrates methods of applying the implant 4500 through the access device 4504. In particular, after the access device 4504 is actuated to the expanded configuration, the implant 4500 is delivered laterally as indicated by the arrow 4540 to a surgical location defined by the distal end 4516 of the access device 4504 at one lateral side of the vertebrae V_1, V_2 and into the interbody space I. In one application, in order to facilitate insertion of the implant 4500, visualization of the surgical site may be achieved in any suitable manner, e.g., by use of a viewing element 4532, as discussed above.

[0339] In one procedure, a gripping apparatus 4580, not shown in **FIGURE 78**, is coupled with one or more portions and/or surfaces of the implant 4500 to facilitate insertion of the implant 4500. In one embodiment, the gripping apparatus 4580 is similar to the tool 2032, described above. The gripping apparatus 4580 has an elongate body 4584 that extends between a proximal end (not shown) and a distal end 4588. The length of the elongate body 4584 is selected such that when the gripping apparatus 4580 is inserted through the access device 4504 to the surgical location, the proximal end extends proximally of the proximal end 4512 of the access device 4504. This arrangement permits the surgeon to manipulate the gripping apparatus 4580 proximally of the access device 4504. The gripping apparatus 4580 has a grip portion 4592 that is configured to engage the implant 4500. In one embodiment, the grip portion 4592 comprises a clamping portion 4596 configured to firmly grasp opposing sides 4598 of the implant. The clamping portion 4596 may further comprise a release mechanism, which may be disposed at the proximal end of the gripping apparatus 4580, to loosen the clamping portion 4596 so that the implant 4500 may be released once delivered to the interbody space I. In another embodiment, the grip portion 4592 comprises a jaw portion with protrusions disposed thereon, such that a portion of the implant 4500 fits within the jaw portion and engages the protrusions. In another embodiment, the grip portion 4592 comprises a malleable material that can conform to the shape of the implant 4500 and thereby engage it. Other means of coupling the gripping apparatus 4580 to the implant 4500 known to those of skill in the art could also be used, if configured to be inserted through the access device 4504.

[0340] As shown in **FIGURE 78**, the implant 4500 may be configured to be engaged by the grip portion 4592 of the gripping apparatus 4580. For example, the implant 4500 could include a tab 4600

configured to be engaged by the grip portion 4592 of the gripping apparatus 4580. In one embodiment, the tab 4600 is configured to fit within a jaw portion and engage the protrusions disposed thereon. In another embodiment, the tab 4600 may be configured to fit within a clamping portion 4596 that can be tightened upon it. In another embodiment, the tab 4600 may be configured to mate closely with a corresponding surface in the grip portion 4592 of the gripping apparatus 4580.

[0341] In one method of delivering the implant 4500 to the surgical location, the gripping apparatus 4580 is coupled with the implant 4500, as described above. The gripping apparatus 4580 and the implant 4500 are advanced into the proximal end 4516 of the access device 4504, to the surgical space 4542, and further into the interbody space I.

[0342] As shown in **FIGURE 79**, in one application, the implant 4020 is delivered into the interbody space I. The first portion 4021 of the implant 4020 may be delivered to the interbody space I first and thereafter coupled with the lower surface of the superior vertebra V_1 defining the interbody space I. As discussed above, each of the first and second portions of each of the implants 4020, 4030 preferably has a generally planar surface. In some embodiments, these surfaces have an element that extends therefrom, which is intended to mate with a corresponding feature, e.g., a hole, formed in the vertebrae V_1, V_2 as discussed above. Next, the second portion 4022 of the implant 4020 may be delivered to the interbody space I through the same or a different access device, as discussed above, and thereafter coupled with the upper surface of the inferior vertebra V_2 defining the interbody space I. Analogous procedures may be performed in connection with the implants 4030, 4110, 4210, 4300, 4400.

[0343] The implant 4500 may have to be temporarily fixed in place until it becomes secure, e.g., until sufficient bone growth occurs between the adjacent vertebrae V_1, V_2 and one or more surfaces of the implant 4500. In other applications, a structure similar to the endcap 4190 could be used to temporarily assist in the securement of the implant 4500 to the adjacent bone structure until the implant 4500 becomes more permanently secure. **FIGURE 79** shows the spine after the implant 4500 has been inserted between the vertebrae V_1, V_2.

[0344] **FIGURES 80-82** provide further, detailed methods by which an interbody space may be prepared for the insertion of an implant 4500 delivered through an access device 4504. The methods illustrated are performed via a lateral approach; however, other approaches are also possible, including those enumerated above.

[0345] **FIGURE 80** illustrates the access device 4504 inserted into a patient in a manner such as those discussed above with reference to **FIGURES 76-79**. Using fluoroscopy in a preferred embodiment to accurately identify the damaged disc, a registration paddle 4600 is inserted through the access device 4504 into the intervertebral disc space. The registration paddle 4600 serves as a place marker to register the location and orientation of the disc that needs to be at least partially replaced with a spinal implant. The registration paddle 4600 preferably has an elongate body that extends between a proximal end and a distal

end. The length of the elongate body is selected such that when the registration paddle 4600 is inserted through the access device 4504 to the surgical location, the proximal end extends proximally of the proximal end of the access device 4504, as shown. This arrangement permits the surgeon to manipulate the registration paddle 4600 proximally of the access device 4504. As is well known to those of skill in the art, the registration paddle's distal end corresponds roughly to the shape and size of the interbody space, such that it cannot twist or move easily.

[0346] With the registration paddle 4600 accurately positioned and oriented, a guide 4605 is then placed over the registration paddle 4600 and slid down to a location proximal the vertebrae. This guide 4605 may then be attached to a vertebra adjacent the interbody space in a number of ways well-known to those of skill in the art. In one application, the guide 4605 may be inserted using a tool similar to the gripping apparatus 4580 described above. In the illustrated embodiment, the guide 4605 is then screwed into the adjacent vertebral body. As will be appreciated, the guide 4605 will be in a particular location and orientation relative to the intervertebral disc. As a result, subsequent disc preparation and implant insertion procedures can be performed relative to this guide 4605 with greater ease and less reliance on endoscopic apparatuses. Of course, many other means may be used to affix the guide at various locations and orientations with respect to the interbody space, as is well known to those of skill in the art.

[0347] **FIGURE 81** illustrates in greater detail one embodiment of a guide 4605 in position on a vertebra adjacent an interbody space. The guide 4605 includes a dovetail guide 4610. Other surgical instruments may have corresponding surfaces that engage with this dovetail guide 4610 in order to guide them to the interbody space in a proper orientation. The guide 4605 itself, with its planar surface 4615, also provides orientation and location information to a surgeon. Using this guide 4605, various instruments may be inserted in proper orientation and position relative to the interbody space. In the illustrated embodiment, an annulotomy has been performed directly adjacent the guide 4605, creating an opening 4618 in the spinal disc's annulus.

[0348] In other embodiments, other means of locating devices relative to the guide 4605 may be used, including simple grooves and milled paths. In still other embodiments, the guide's surface may not be planar, but may have other geometries that help to guide instruments to the vertebrae. In another embodiment, the guide 4605 may not provide more guidance than its own planar surface running roughly parallel to the intervertebral disc space.

[0349] **FIGURES 82A, 82B** and **82C** show an embodiment of the guide 4605 facilitating the production of milled patterns on the vertebrae in order to facilitate the introduction of a spinal implant. In the illustrated embodiment, the implant to be inserted has an H-formation that faces the vertebral body. If the vertebral body were to have an H-formation 4628 milled from its bone, then the implant would seat better within the disc space and heal more quickly. (See **FIGURES 82A** and **82B**.)

[0350] In the illustrated embodiment, the method of performing this preparatory operation is to have a template 4629 milled in the guide 4605. A mill 4630 is provided that has a cutting edge 4632 at its distal end and a protrusion 4634 near its distal end. The distance chosen between the protrusion 4634 and cutting edge 4632 is chosen to correspond to the distance between the template 4629 in the guide 4605, and a corresponding milled location 4628 in the intervertebral space. Thus, as illustrated in **FIGURE 82C**, the cutting edge 4632 and the protrusion 4634 of the mill 4630 are inserted through the access device 4504. Before cutting, the protrusion 4634 is located within the template 4629 of the guide 4605. The surgeon then follows the template with the mill 4630 in order to make a similar set of milled grooves 4628 within the vertebral body. This process makes the surgical procedure faster and more efficient. Some procedures may employ a guide, such as the guide 4605, and a steerable instrument, such as those discussed herein, to provide a combination of advantages.

[0351] Of course, other uses may also be found for the guide 4605. In one embodiment, not shown, the guide may facilitate the insertion of the implant 4500, by providing the necessary orientation and location information. In another embodiment, the guide 4605 may be used to facilitate the removal or adjustment of an implant that has been previously inserted. In other embodiments, the guide 4605 may be used for a number of other procedures that require knowledge of location and orientation near the spinal column. For example, pedicle screws may be inserted more accurately using the guide 4605, and spinal nucleus replacement may also be facilitated.

[0352] Although the forgoing procedures are described in connection with a single level lateral or postero-lateral procedure, other procedures are possible. For example, multiple level disc replacement could be performed with the expandable conduit 20 or other suitable access device. As discussed above, other applications are also possible in which the access device 4504 is not expanded prior to delivery of the implant 4500. In such applications, the access device 4504 remains in the first configuration while the steps described above are performed, or a non-expandable access device may be provided. Also, other approaches could be adopted, e.g., anterior, posterior, transforaminal, or any other suitable approach. In one application, the implant 4500 is inserted at the L5-S1 vertebrae or at the L5-L4 vertebrae anteriorly through the access device 4504. Also, a motion preserving disc replacement procedure could be combined with a fusion procedure in two different interbody spaces, e.g., two adjacent interbody spaces.

[0353] Although the methods discussed above are particularly directed to the insertion of an implant 4500, the access device 4504 may also be used advantageously to remove the implant 4500. It may be desirable to remove the implant 4500 if the patient's spine condition changes or if the performance of the implant 4500 is compromised, e.g., through wear or subsidence (reduction in the height of the implant). In one application, the tab 4600 disposed on the implant 4500 may be further configured to facilitate subsequent removal. The gripping apparatus 4580 may also be further configured to facilitate removal as well as insertion. By providing minimally invasive access to the interbody space I, the access device 4504 may be

used analogously as described above with reference to the removal of the natural disc material, to remove a previously inserted implant 4500. Upon removal of the implant 4500, various subsequent procedures may be performed in the interbody space I. For example, a new implant 4500 may be inserted through the access device 4504 into the interbody space I. Other procedures that could be performed after removing the previously inserted implant 4500 include the insertion of a fusion device, such as the spinal implant 2010, where it is determined that fusion is a more suitable treatment than disc replacement. Such a determination may arise from a change in the condition of the spine, e.g., due to the onset of osteoporosis, that makes disc replacement inappropriate.

[0354] Another procedure that may be performed through the access device 4504 involves replacement of two or more joints. Some patients who are suffering from degenerative disc disease also suffer from degenerative facet joint disease. While replacement of both a disc and a facet joint in such a patient is possible during the same operation using other methods, such an operation would be very complicated because it would likely require that the spine be approached both anteriorly and posteriorly. In contrast, in some approaches described hereinabove, the access device 4504 would provide sufficient access to both the interbody space I to facilitate replacement of a disc with the implant 4500 and to one or more facet joints to facilitate replacement of one or more facet joints. For example, the postero-lateral approaches indicated by the arrows 4544, 4552 could provide access to a disc in the interbody space I and an adjacent facet joint. In another method, first and second access devices could be applied in any combination of the lateral and postero-lateral approaches indicated by the arrows 4540, 4548, 4544, and 4552, or other approach, to provide access to a disc in the interbody space I and an adjacent facet joint. In one method three or more joints are replaced, e.g., a disc in the interbody space I and the two corresponding, adjacent facet joints by way of one or more access device applied along any combination of the approaches 4540, 4544, 4548, and 4552, or other approach.

[0355] The foregoing methods and apparatuses advantageously provide minimally invasive treatment of disc conditions in a manner that preserves some degree of motion between the vertebrae on either side of a replaced disc. Accordingly, trauma to the patient may be reduced thereby, and recovery time shortened. As discussed above, many of the implants provide a more normal post-recovery range of motion of the spine, which can reduce the need for additional procedures.

[0356] It will be understood that the foregoing is only illustrative of the principles of the invention, and that various modifications, alterations, and combinations can be made by those skilled in the art without departing from the scope and spirit of the invention.

B. Apparatuses, Systems and Methods for Replacing a Nucleus Pulposus and Preserving Motion

[0357] Another type of procedure that can be performed by way of the systems and apparatuses described herein involves replacement of one or more of a patient's nucleus pulposi with a replacement disc nucleus, e.g., a prosthetic device, that provides the functions of the natural nucleus

pulposus while preserving or restoring a degree of normal motion after recovery. A variety of replacement disc nuclei that may be applied to replace a damaged or degenerating nucleus are described below. The access devices and systems described herein enable these devices and methods associated therewith to be practiced minimally invasively.

1. Replacement Disc Nucleus Comprising a Pliable Enclosure

[0358] **FIGURE 83** shows a first embodiment of a replacement disc nucleus 5000 that comprises a pliable enclosure 5002. As used herein, the term "enclosure" is a broad term and is used in its ordinary sense and includes a structure within which a volume may be at least partially defined. In one embodiment, the enclosure 5002 formed of a porous material that permits body fluids to diffuse therethrough. The enclosure 5002 may be formed as a bag, a sac, a frame-like structure, or any other suitable arrangement.

[0359] The enclosure 5002 preferably defines a volume 5004 which may be increased and / or decreased during application to a patient's spine. For example, the enclosure 5002 is capable of having a first configuration prior to insertion into an intervertebral disc space, wherein the volume 5004 is relatively small and a second configuration after inserted into a patient, wherein the volume 5004 is relatively large. The enclosure 5002 may be compressed prior to insertion, and then expanded (or allowed to expand) during or after insertion. In one application, the enclosure 5002 is compressed prior to insertion into an intervertebral disc space and is expanded (or permitted to expand) before a filler medium is advanced into the volume 5004 defined by the enclosure 5002.

[0360] In one application, an expandable member is delivered into the volume 5004, which had previously been reduced in size, e.g., by compressing the enclosure 5002. The expandable member is expanded to expand the enclosure 5002 to increase the size of the volume 5004 before the filler medium is delivered. In one embodiment, the enclosure 5002 includes a balloon or bladder configured to facilitate the expansion of the enclosure 5002 from the compressed state to the expanded state. In one application, the balloon or bladder is filled with a suitable fluid (e.g., liquid or gas) to inflate the balloon or bladder and thereby to expand the enclosure 5004. These and other methods related to the enclosure 5002 are discussed in greater detail below in connection with **FIGURES 90 -95**.

[0361] The enclosure 5002 preferably includes an aperture 5008 that may be opened and closed as needed. In the illustrated embodiment, the aperture 5008 is formed by retracting a flap 5012 or other similar structure. In another embodiment, a slit may be provided in addition to or in place of the flap 5012. In one embodiment, the flap 5012 can be securely closed so that the filler medium generally is contained within the volume 5004. Secure closure of the flap 5012 may be achieved by suturing the flap 5012 closed or by providing some other closure mechanism or device between the flap 5012 and the adjacent portion of the enclosure 5002.

[0362] Where the enclosure 5002 is configured to be filled by a filler medium, the filler medium may be any suitable medium, e.g., morselized nucleus pulposus from the patient, allograft material, or other biocompatible materials. The filler medium may also be allograft nucleus pulposus, xenograft nucleus

pulposus, other tissue and/or synthetic materials such hydrogels. In one application, the nucleus material removed prior to insertion of the enclosure 5002 is ground up, e.g., morselized, and placed inside the enclosure 5002 to expand the enclosure 5002.

[0363] Various techniques may be performed to prevent the enclosure 5002 or filler medium from migrating from the position in which the enclosure 5002 and filler medium are originally placed. For example, one or both of the filler medium or the enclosure 5002 may be configured to encourage ingrowth of bone between an adjacent vertebra and the replacement disc nucleus 5000. In another arrangement, the filler medium is physically coupled with, e.g., woven or stapled, into the enclosure 5002 to deter migration of the inflation medium from the volume 5004. In another embodiment, the enclosure 5002 is configured to receive a suture or other structure of device, e.g., a staple, configured to couple with enclosure 5002 with one or more anatomical aspect, such as an inside surface of a disc annulus.

[0364] In one embodiment, the enclosure 5002 is or contains a self-expanding member. In application, the self-expanding enclosure may be delivered in a compressed configuration, as discussed above, and then released and permitted to expand within an intervertebral disc space. The self-expanding enclosure may include one or more spring-like hoops separated by an elastic material, such as rubber or silicone. The enclosure, or a portion of the material separating the hoops of the enclosure, could also include a shape memory material that enables the enclosure to change from a shape with an aperture (to allow insertion of a filler medium) to a shape with a small slit (to close the aperture).

[0365] In one application, as discussed more fully below in connection with **FIGURES 90 - 94**, an aperture may be formed in an annulus of a natural disc, providing a door-like flap in the annulus tissue. The aperture in the annulus may be configured such that the enclosure 5002 in the collapsed or compressed state may pass therethrough. The enclosure 5002 is then placed inside the intervertebral space, and actuated to the expanded state in any suitable manner. In some applications, fasteners such as sutures, staples, and so forth, may be inserted through the aperture 5008 into the volume 5004 and through at least a portion of, e.g., a wall of, the enclosure 5002 and into an anatomical structure, such as disc tissue, e.g., annulus tissue.

[0366] Further details relating to replacement disc nuclei having pliable enclosures may be found in U.S. Patent Application No. 10/120,763 filed on April 11, 2002, and published as Publication No. 2002/0165542 on November 7, 2002, which is hereby incorporated herein by reference in its entirety.

2. Replacement Disc Nucleus Including a Hydrogel

[0367] **FIGURES 84A - 85** illustrate another embodiment of a replacement disc nucleus 5050 that includes a hydrogel. In one embodiment, the replacement disc nucleus 5050 includes a hydrogel core 5054, and a constraining jacket 5058. The constraining jacket 5058 is secured about the hydrogel core 5054 by closures 5062 located at opposite ends of the constraining jacket 5058.

[0368] The replacement disc nucleus 5050 is described below as having a first, pre-replacement disc nucleus shape and a second, post-replacement disc nucleus shape. To this end, because

the hydrogel core 5054 is dehydrated prior to implant and hydrated following implant, the pre-implant shape can also be referred to as a dehydrated shape; whereas the post-implant shape is referred to as a hydrated shape. As a point of reference, **FIGURE 84A** depicts the dehydrated shape; whereas **FIGURE 85** depicts the hydrated shape.

[0369] In one embodiment, the hydrogel core 5054 is configured to imbibe fluids, expanding from a dehydrated state (shown in **FIGURE 84A**) to a hydrated state (**FIGURE 85**). In this regard, the hydrogel core 5054 is formulated as a mixture of hydrogel polyacrylonitrile in one embodiment. In particular, acrylamide and acrylonitrile (block co-polymer) are used in one embodiment. Alternatively, the hydrogel core 5054 can be any hydrophilic acrylate derivative with a unique multi-block co-polymer structure or any other hydrogel material having the ability to deform and reform in a desired fashion in response to placement and removal of loads, such as a keratin-derived hydrogel. Even further, a biologically safe polymer that can imbibe fluids while maintaining its structure under various stresses is acceptable. For example, the hydrogel core 5054 can be formulated as a mixture of polyvinyl alcohol and water. Much like a natural nucleus, the hydrogel core 5054 will initially swell from a dehydrated state as it absorbs fluid. When hydrated, the hydrogel core 5054 will have a water content of 25-90 percent in one embodiment. The hydrogel material used for the hydrogel core 5054 in the first embodiment is manufactured under the trade name HYPAN® by Hymedix International, Inc. of Dayton, N.J.

[0370] As shown in **FIGURE 84A**, the hydrogel core 5054 defines a leading end 5066, a central portion 5070 and a trailing end 5074. As described in greater detail below, the leading end 5066 and the trailing end 5074 are in reference to a preferred orientation of the replacement disc nucleus 5050 during an implantation procedure. For the purposes of this disclosure, directional terminology, such as "leading" and "trailing," are with reference to one possible orientation of the replacement disc nucleus 5050 during implantation. It should be understood, however, the replacement disc nucleus 5050 can be orientated in any direction relative to a nucleus cavity, also referred to herein as an interbody space. As such, the directional terms are provided for purposes of illustration only.

[0371] As a point of reference, the replacement disc nucleus 5050 is defined by a width (x-axis in **FIGURE 84A**), a length (y-axis in **FIGURE 84A**) and a height (z-axis in **FIGURE 84A**). With this in mind, the hydrogel core 5054, and thus the replacement disc nucleus 5050, is fabricated to assume a streamlined shape in the dehydrated state. The term "streamlined" is with reference to the hydrogel core 5054 being configured, in the dehydrated state, to taper or decrease in height (z-axis) from the central portion 5070 to the leading end 5066. In one embodiment, in the dehydrated state, the hydrogel core 5070 is further configured to taper or decrease in height (z-axis) from the central portion 5070 to the trailing end 5074. With this preferred embodiment, then, opposing sides of the hydrogel core 5054 are generally convex, resulting in the generally convexo-convex shape. While the taper or decrease in height (z-axis) is preferably uniform, other designs are acceptable. The "streamlined" shape in the dehydrated state relates to the central portion 5070

tapering in height to the leading end 5066. Further, in one embodiment, the central portion 5070 also tapers in height to the trailing end 5074.

[0372] In addition to the above-described streamlined shape, in one embodiment, a top, cross-sectional view shows the central portion 5070 of the hydrogel core 5070 as being curved. More particularly, opposing sides of the hydrogel core 5054 curve in a generally symmetrical fashion from the leading end 5066 to the trailing end 5074. Alternatively, the opposing side may be linear, non-symmetrical etc.

[0373] Completely surrounding the hydrogel core 5054 is the constraining jacket 5058. The constraining jacket 5058 is preferably a flexible tube made of tightly woven high molecular weight, high tenacity polymeric fabric. In one embodiment, high molecular weight polyethylene is used as the weave material for the constraining jacket 5058. However, polyester or any high tenacity polymeric material can be employed, and carbon fiber yarns, ceramic fibers, metallic fibers, etc., also are acceptable.

[0374] The constraining jacket 5058 is preferably made of fibers that have been highly orientated along their length. As a result, the constraining jacket 5058 material, while flexible, has little elasticity or stretch. The constraining jacket 5058 defines a generally fixed maximum volume, including a generally fixed length (y-axis of **FIGURE 84A**). In one embodiment, the generally fixed maximum volume of the constraining jacket 5058 is less than a theoretical volume of the hydrogel core 5054 if allowed to completely hydrate without constraint. Thus, because the hydrogel core 5054 has a natural, fully hydrated volume greater than the constraining jacket 5058, the constraining jacket 4058 will be tight about the hydrogel core 5054 when hydrated, as described in greater detail below. Additionally, the volume differential between the constraining jacket 5058 and the hydrated hydrogel core 5054 serves to extend the useful life of the replacement disc nucleus 5050. In particular, the constraining jacket 5058 effectively prevents the hydrogel core 5054 from reaching its natural hydration level. Consequently, the hydrogel core 5054 will have a generally constant affinity for imbibing additional fluid. Finally, the hydrogel core 5054 is preferably configured such that in the dehydrated state, the hydrogel core 5054 has a length approximating the generally fixed maximum length of the constraining jacket 5058. Thus, the hydrogel core 5054 causes the constraining jacket 5058 to be relatively taut along its length (y-axis). Notably, the hydrogel core 5054 in the dehydrated state does not encompass the entire available volume of the constraining jacket 5058.

[0375] In one embodiment, the preferred woven construction of the constraining jacket 5058 creates a plurality of small openings 5078. Each of the plurality of small openings 5078 preferably is large enough to allow bodily fluids to interact with the hydrogel core 5054 otherwise maintained within the constraining jacket 5058. However, each of the plurality of small openings 5078 preferably is small enough to prevent most if not all of the hydrogel core 5054 from escaping. Each of the plurality of small openings 5078 has an average diameter of about 10 micrometers in one embodiment. Other dimensions of the small openings 5078 are acceptable as well. In this regard, although the constraining jacket 5058 has been described as having a woven configuration, any other configuration having a semi-permeable or porous

attribute can be used. Finally, the constraining jacket 5058 material preferably allows for tissue in-growth and is textured to provide a grip or purchase within a disc space.

[0376] As indicated above, the hydrogel core 5054 is configured to expand from the dehydrated shape, shown in **FIGURE 84A**, to a hydrated shape, shown in **FIGURE 85**, following implantation. Manufacture of the hydrogel core 5054 is described in greater detail below. Generally speaking, the hydrogel core 5054 is constructed such that the hydrated shape is different from the dehydrated shape. In other words, the hydrogel core 5054 has a streamlined shape in the dehydrated state to facilitate implant, and preferably has a shape generally corresponding to the shape of a portion of a nucleus cavity (not shown) in the hydrated state. One example of the hydrated replacement disc nucleus 5050 is shown in **FIGURE 85**. In the hydrated state, the hydrogel core 5054, and thus the replacement disc nucleus 5050, defines an anterior face 5082 (partially hidden in **FIGURE 85**), a posterior face 5086, and opposing end plate faces 5090, 5094 (partially hidden in **FIGURE 85**). The opposing end plate faces 5090, 5094 may also be referred to as a superior face and an inferior face, respectively. For the purposes of this disclosure, directional terminology such as "anterior," "posterior," "superior," and "inferior" may be with reference with one possible orientation of the replacement disc nucleus 5050 within a nucleus cavity. Also, the terms "posterior" and "posteriorly" are used in their ordinary sense (i.e., from or through the rear-facing side of the patient) and are broad terms and they include an approach along any line generally behind and between the two lateral sides of the patient. It should be understood, however, that due to its unique sizing, the replacement disc nucleus 5050 can be orientated in any direction relative to a nucleus cavity or the world in general. As such, the directional terms are provided for purposes of illustration only, and should not be interpreted as limitations. As a point of reference, **FIGURE 85** again identifies the leading end 5066 and the trailing end 5074.

[0377] A comparison of the replacement disc nucleus 5050 in the dehydrated state (**FIGURE 84A**) with that in the hydrated state (**FIGURE 85**) illustrates the preferred transition in shape of the hydrogel core 5054. The hydrogel core 5054 has transitioned, upon hydration, from the streamlined configuration of **FIGURE 84** to a rectangular configuration of **FIGURE 85**. In particular, in one embodiment, the hydrogel core 5054 in the hydrated state does not taper from the central portion 5070 to the leading end 5066 or the trailing end 5074. Instead, the hydrogel core 5054 has a relatively uniform height (z-axis in **FIGURE 85**). In other words, with hydration, the hydrogel core 5054 transitions from a substantially convexo-convex cross-sectional shape to a rectangular (or plano-plano) shape. Further, in the hydrated state, the central portion 5070 of the hydrogel core 5054 is no longer curved along its length. As described in greater detail below, the replacement disc nucleus 5050 in the hydrated state generally adheres to the spacing requirements of a particular disc space.

[0378] This replacement disc nucleus 5050 preferably provides at least one of the following benefits: (a) restores and maintains the height of the damaged disc space; (b) restores and tightens the natural annulus to stop further degeneration and permit its healing; (c) restores the normal load-unload cycling

and thus flushes out toxic by-products, bringing in fresh nutrients to the disc space; (d) allows a near-normal range of motion; and (e) relieves the movement-induced discogenic pain of the vertebral segment.

[0379] In addition, the replacement disc nucleus 5050 is advantageously insertable by way of a minimally invasive procedure as described herein. With reference to **FIGURES 90 – 95**, the replacement disc nucleus 5050 can be applied to a patient by way of a minimally invasive access device which may be configured when inserted to provide greater access at a distal end thereof, e.g., near a surgical location near the spine. The term "access device" is used in its ordinary sense (i.e. a device that can provide access) and is a broad term and it includes structures having an elongated dimension and defining a passage, e.g., a cannula or a conduit. The increased access at the surgical location enables the surgeon to prepare the disc annulus through the access device and to insert the replacement disc nucleus 5050 into the intervetebral space through the access device. Thus, the minimally invasive apparatuses and methods enable the to surgeon to reduce the trauma cause by the procedure by which the replacement disc nucleus 5050 is inserted and to provide other benefits, such as reducing the length of recovery time.

[0380] Further details relating to this second replacement disc nucleus may be found in U.S. Patent No. 6,602,291, issued August 5, 2003, which is hereby incorporated herein by reference in its entirety.

3. Substantially Mushroom-Shaped Replacement Disc Nucleus

[0381] **FIGURES 86 and 87** show another embodiment of a replacement disc nucleus 4100 that is substantially mushroom shaped. **FIGURE 86** illustrates one application of the replacement disc nucleus 5100. The natural disc 5104, which is located between the vertebrae V_1 and V_2, as shown in **FIGURE 86,** is degenerated. The replacement disc nucleus 5100 is surgically embedded in the inter-vertebral space between vertebrae V_1 and V_2, and inside an annulus fibrosus 5108, as discussed in greater detail below in connection with **FIGURES 73-77**.

[0382] The replacement disc nucleus 5100 may comprise a solid polymer flattened into an oval disk. In general, any solid biocompatible material can be used, including various polymers and plastics, titanium, stainless steel, tantalum, chrome cobalt alloys, etc. Ultra-high molecular-weight polyethylene is presently preferred so that metal radiograph markers may be strategically placed in the replacement disc nucleus 5100.

[0383] As shown in **FIGURE 87**, the replacement disc nucleus 5100 has a top half 5112 that is domed and has a crest that is about three times higher ("3h") than the crest ("1h") on a domed bottom half 5116. The replacement disc nucleus 5100 resembles a partially collapsed ellipsoid. Both top and bottom surfaces preferably are convex. The outside diameter of the replacement disc nucleus 5100 can vary, e.g., in the range of twenty to thirty-six millimeters. The overall height can also vary, e.g., in the range of eight to sixteen millimeters. The actual dimensions required depend on the size of the patient and the exact site to receive the replacement disc nucleus 5100. Such required sizes are discernable from patient radiographs, CT-scans, and MRI-scans.

[0384] In one embodiment, a peg 5120 extends down from the middle of the bottom-domed surface 5116. The peg 5120 is typically two to four millimeters long and is used to pin the replacement disc nucleus 5100 to the lower vertebrae, e.g., vertebrae V_2 in **FIGURE 86**. A pair of metal radiograph markers 5124 and 5128, e.g., one in the peg 5120 and one on an outside edge, are placed so that radiographs can be used to determine the replacement disc nucleus's in situ position. The replacement disc nucleus 5100 is surgically implanted into the hollowed out intervertebral space through a flap cut in the natural annulus fibrosus. Such "hollowing out" is commonly called a discectomy. The lower vertebra V_2 is prepared to receive the peg 5120 by clearing the material covering the top of the bone matrix. Bone cement is used around the peg 5120 to ensure a tight fit and immobile attachment of the disc to the lower vertebrae V2.

[0385] In one embodiment, the material making up the replacement disc nucleus 5100 is selected from a group of biocompatible, rigid or semi-rigid materials, including: titanium, stainless steel, surgical alloys, molybdenum alloys, cobalt chromium alloy, non-absorbable polymers, etc. Some embodiments of the replacement disc nucleus 5100 mimic the natural load-relieving, compressive functionality of a natural nucleus pulposus, while other embodiments do not. Further details relating to this replacement disc nucleus may be found in U.S. Patent No. 6,146,422, issued November 14, 2000, which is hereby incorporated herein by reference in its entirety.

4. Injectable Replacement Disc Nucleus

[0386] **FIGURE 88** shows another embodiment of a replacement disc nucleus 5200 applied to a segment of a patient's vertebral column. As shown, the replacement disc nucleus 5200 is interposed between adjacent ones of the individual vertebrae V_1 and V_2. The replacement disc nucleus 5200 is surrounded by the fibrillar outer annulus fibrosus 5204 of the patient's natural vertebral disc following removal of the gelatinous nucleus pulposus. The fibrillar outer annulus 5204 thus bounds and defines an inner cavity into which the replacement disc nucleus 5200 is injected in situ. This replacement disc nucleus 5200 may comprise a number of injectable materials, including hydrogels, thermoplastic elastomers, or a proteinaceous biopolymer, which thus fill the void space left following removal of the natural nucleus pulposus of the patient's natural vertebral disc. The replacement disc nucleus 5200 thus acts as a shock-absorber of sorts similar to the natural functions attributable to the removed gelatinous core.

[0387] In one embodiment, a biologically inert curable thermoplastic is injected through the annulus fibrosus and allowed to cure within the patient, until it has achieved a viscosity and hardness sufficient to support normal postural compressive loads. In another embodiment, virtually any suitable proteinaceous biopolymer may be used. In this regard, the term "proteinaceous biopolymer" and like terms mean a polymeric or copolymeric material which contains one or more units in the polymer chain comprised of natural, synthetic or sequence-modified proteins or polypeptides, and mixtures and blends of such polymeric and/or copolymeric materials.

[0388] One preferred biopolymer that may be used is a cross-linked reaction product of a two part mixture initially comprised of:

[0389] Part A: a water-soluble proteinaceous material of about 27-53% by weight of the mixture, and

[0390] Part B: di- or polyaldehydes present in a weight ratio of one part by weight to every 20-60 parts of protein present by weight in the mixture and water, optionally containing non-essential ingredients to make up the balance of the composition.

[0391] Part A of the mixture is preferably substantially an aqueous solution of a proteinaceous material of human or animal origin. Albumins including ovalbumins are preferred proteins, and serum albumins of human or animal origin are particularly preferred. The proteinaceous material may be a purified protein or a mixture in which the proteins such as serum albumins are the predominant ingredients. For example, the solid mixtures obtained by dehydration of blood plasma or serum, or of commercial solutions of stabilized plasma proteins, can be used to prepare Part A. These mixtures, generally referred to as plasma solids or serum solids, are known to contain albumins as their major ingredients, of the order of 50-90%. As used herein, the term "plasma" refers to whole blood from which the corpuscles have been removed by centrifugation. The term "serum" refers to plasma which has additionally been treated to prevent agglutination by removal of its fibrinogen and/or fibrin, or by inhibiting the fibrin clot formation through addition of reagents, such as citrate or EDTA. The proteinaceous material may also contain an effective amount of hemoglobin.

[0392] Part B may substantially be an aqueous solution of di- or polyaldehydes. A wide range of these substances exist, and their usefulness is restricted largely by availability and by their solubility in water. For example, aqueous glyoxal (ethandial) is useful, as is aqueous glutaraldehyde (pentandial). Water soluble mixtures of di- and polyaldehydes prepared by oxidative cleavage of appropriate carbohydrates with periodate, ozone or the like are also useful. Glutaraldehyde is the preferred dialdehyde ingredient of Part B. When Parts A and B are brought together, the resultant product rapidly hardens to a strong, flexible, leathery or rubbery material within a short time of mixing, generally on the order of 15-30 seconds. One material that may be used in this embodiment is commercially available from CryoLife, Inc. of Kennesaw, Ga. under the registered trademark "BIOGLUE". See also, U.S. Patent No. 5,385,606, which is hereby incorporated by references herein in its entirety.

[0393] The two components A and B noted above are either premixed and then applied, or simultaneously mixed and delivered through an in-line mixing/dispensing tip during the filling of the tissue-defined cavity. Upon reaction of the two components, the resulting biomaterial is a hydrogel that adheres to the surrounding tissue, intercalates into the voids of the surrounding tissues, is space filling, and is mechanically and biologically stable for some time. The material may be solid or sponge-like in appearance. Furthermore, it may contain organic or inorganic salts or other particulate matter to modify the physical properties of the resulting bioprosthetic device. Further details of the replacement disc nucleus 5200 may be found in U.S. Patent Application No. 09/983,537, filed on October 24, 2001, which has been published as U.S.

Publication No. 2002/0049498, and U.S. Patent Application 09/908,056 filed on July 18, 2001, which are hereby incorporated herein by reference in their entirety.

5. Disc-Like Replacement Disc Nucleus

[0394] **FIGURE 89** shows another embodiment of a replacement disc nucleus 5150. In this embodiment, material forms a disc approximately the size of a natural, biological nucleus pulposus. This disc-like structure, which comprises the replacement disc nucleus 5150, is configured to be inserted into the patient's spine. Many different materials may be used. In one embodiment, hybrid materials used to induce and/or guide reformation of intervertebral disc tissue comprise biodegradable substrates that make up the disc. Biodegradable means that the substrate degrades into natural, biocompatible byproducts over time until the substrate is substantially eliminated from the implantation site and, ultimately, the body. In one embodiment, the rate of biodegradation of the substrate is preferably less than or equal to the rate of intervertebral disc tissue formation, such that the rate of tissue formation is sufficient to replace the support material that has biodegraded.

[0395] Further details relating to this embodiment of the replacement disc nucleus 5150 may be found in U.S. Patent No. 6,240,926, issued June 5, 2001, which is hereby incorporated herein by reference in its entirety and in U.S. Patent Application No. 10/167,503 filed on June 13, 2002, which also is hereby incorporated by reference in its entirety.

6. Further Methods of Applying a Replacement Disc Nucleus

[0396] **FIGURES 90-95** more particularly illustrate methods whereby a variety of embodiments of replacement disc nuclei, collectively referred to as a replacement disc nucleus 5300, may be delivered through an access device 5304 and implanted in an intervertebral space I defined between a first vertebra V_1 and a second vertebra V_2 and within an annulus fibrosus A. The replacement disc nucleus 5300 may be any suitable replacement disc nucleus, e.g., any of the replacement disc nucleuses 5000, 5050, 5100, 5150, 5200, or any other suitable replacement disc nucleus. Some methods or techniques of implanting the replacement disc nucleus 5300 may be similar to the methods described above in connection with **FIGURE 51** for implanting the fusion implant 2010.

[0397] In one method, access to the intervertebral space I is provided by inserting a retractor or access device 5304 into the patient. The access device 5304 may be configured in a manner similar to the expandable conduit 20 and may be inserted in a similar manner, e.g., over a dilator. The access device 5304 preferably has an elongate body 5308 that has a proximal end 5312 and a distal end 5316. The elongate body 4308 has a length between the proximal end 5312 and the distal end 5316 that is selected such that when the access device 5304 is applied to a patient during a surgical procedure, the distal end 5316 can be positioned inside the patient adjacent a spinal location, and, when so applied, the proximal end 5312 preferably is located adjacent the skin of the patient or outside the patient at a suitable height.

[0398] In one embodiment, the elongate body 5308 comprises a proximal portion 5320 and a distal portion 5324. The proximal portion 5320 may have a generally oblong or oval shape cross-section, a

generally circular shape cross-section, or any other suitable shaped cross-section. The term "oblong" is used in its ordinary sense (i.e. having an elongated form) and is a broad term and it includes a structure having a dimension, especially one of two perpendicular dimensions, such as, for example, width or length, that is greater than another. The term "oval" is used in its ordinary sense (i.e., egg like or elliptical) and is a broad term and includes oblong shapes having curved portions and oblong shapes having parallel sides and curved portions. The distal portion 5324 preferably is expandable, as discussed above in connection with the expandable conduit 20, to the configuration illustrated in **FIGURES 90-95**. At least one passage 5328 extends through the elongate body 5308 between the proximal end 5312 and the distal end 5316. Further details of various additional embodiments of the access device 1504 may be found in U.S. Patent Application Serial No. 10/678,744, filed October 2, 2003, entitled MINIMALLY INVASIVE ACCESS DEVICE AND METHOD, which is hereby incorporated by reference herein in its entirety.

[0399] **FIGURE 92** shows that the access device 5304 is configured to be coupled with a viewing element 5332 in one embodiment. The distal portion 5324 of the access device 5304 has an aperture 5336 into which the viewing element 5332 can be inserted, such that a proximal portion of the viewing element 5332 lies external to the proximal portion 5320, and a distal portion of the viewing element 5332 lies within the distal portion 5324 of the access device 5304. In another embodiment, the viewing element 5332 may extend within the access device 5304 substantially entirely the length of the passage 5328. In other embodiments, the viewing element 5332 may be moved to the surgical location entirely externally to the access device 5304. The viewing element 5332 may be further configured to be removed from the access device 5304 during the procedure, as required.

[0400] The viewing element 5332 may be any suitable viewing element or portion thereof, such as an endoscope, a camera, loupes, a microscope, a lighting element, or a combination of the foregoing. The viewing element 5332 may be an endoscope, such as the endoscope 500, and a camera, which capture images to be displayed on a monitor, as discussed above.

[0401] The access device may be inserted generally posteriorly. Also, the terms "posterior" and "posteriorly" are used in their ordinary sense (i.e., from or through the rear-facing side of the patient) and are broad terms and they include an approach along any line generally behind and between the two lateral sides of the patient. In the illustrated methods, the distal end 5316 of the access device 5304 is inserted postero-laterally, to a surgical location adjacent to at least one vertebra and preferably adjacent to two vertebrae, e.g., the first vertebra V_1 and the second vertebra V_2, to provide access to at least a portion of the intervertebral space I. This approach is illustrated in the solid-line schematic representation of the access device 5304. In different methods, the access device 5304 may be inserted from a variety of different angles, e.g., posteriorly from directly between adjacent transverse processes to the more postero-lateral approach of **FIGURES 90-95**. These other example approaches are shown by the dashed line schematic representation of the access device in **FIGURE 90**. In other methods, the access device 5304 may be inserted laterally,

anteriorly, or from other approaches to provide access to at least a portion of the interbody space I. As discussed above, the access device 5304 can have a first configuration for insertion to the surgical location over the interbody space I and a second configuration wherein increased access is provided to the interbody space I. **FIGURES 90-95** show that the second configuration may provide a cross-sectional area at the distal end 5316 that is larger than that of the first configuration at the distal end 5316. The distal portion 5324 of the access device 5304 may be expanded from the first configuration to the second configuration, as discussed above in connection with the skirt portion 24, using the expander apparatus 200. When so expanded, the distal portion 5324, at the distal end 5316, defines a surgical space that exposes a portion of an external surface of an annulus A.

[0402] As discussed above, in one embodiment, the access device 5304 has a substantially circular cross-sectional shape in the proximal portion 5320. The access device 5304 may further have a circular cross-section near the proximal end 5312, near the distal end 5316, at the proximal and distal ends 5312, 5316, and from the proximal end 5312 to the distal end 5316. As discussed above, in another embodiment, the access device 5304 has an oblong cross-sectional shape in the proximal portion 5320. In particular, the access device 5304 may have an oblong cross-section near the proximal end 5312, near the distal end 4316, at the proximal and distal ends 5312, 5316, and from the proximal end 5312 to the distal end 5316.

[0403] **FIGURE 93 and 94** show that an access device 5304a may also be provided that has a distal end 5316a shaped to follow a contour of the patient's anatomy. In one embodiment, the distal end 5316a of an access device 5304 is partially concave to complement the convex shape of the patient's intervertebral space I. When the concave distal end 5316a is placed adjacent the convex vertebral surface, the concave distal end 5316a of the access device 5304a more completely seals off the surgical location from other tissues, and provides a more defined surgical location than is possible with a flat distal end. In other embodiments, the distal portion 5324 of an access device 5304 may be otherwise shaped or configured to more closely contour the anatomy to which it will provide access. These configurations may provide increased, or more precise access to certain anatomical spaces.

[0404] **FIGURE 95** shows that an access device 5304b may be further configured such that a distal portion 5324b of the access device 5304b can be advanced into an aperture 5340 in the annulus fibrosus A. It may be configured such that the distal portion 5324b lies at least partially within the aperture 5340 in the tissue defining the annulus fibrosus A, or such that the distal portion 5324b extends beyond the aperture 5340 in the annulus fibrosus A into the intervertebral space I. In one embodiment, the transverse size, e.g., diameter, of the access device 5304b may be made substantially smaller than the transverse size, e.g., diameter, of the access device 5304 or the access device 5304a. The smaller diameter of the access device 5304b may provide a closer connection with the intervertebral space I that defines the surgical location, or enlarge an annulotomy (a hole in the annulus fibrosus A), depending on where the distal portion

5324b is expanded. According to one method of enlarging an annulotomy, the distal portion 5324b of the access device 5304b is sized to fit within an aperture in the annulus fibrosus A in a first configuration, but enlarges the aperture when actuated to a second configuration (illustrated by the dashed lines in **FIGURE 95**). Another advantage of the enlargement of the distal portion 5324b is that contact of the distal portion 5324b with the annulus fibrosus A causes the access device 5304b to be tethered to the disc so that movement with respect to the disc can be kept at a minimum. In other applications, the distal portion 5324b is expanded to engage the annulus fibrosus A to limit movement of the access device 5304b but not so much as to enlarge the annulus fibrosus A significantly.

[0405] In some methods of applying the replacement disc nucleus 5300, a second access device, such as an expandable conduit 20 or other suitable access device, may be inserted into the patient. For example, a second access device could be inserted through a postero-lateral approach on the opposite side of the spine, as indicated by an arrow 5348 on **FIGURE 90**, to provide access to at least a portion of an intervertebral space, e.g., the intervertebral space I, on the contralateral side of the spine. Where provided, the second access device may provide access to the interbody space I at about the same time as the first access device 5304 or during a later or earlier portion of a procedure. In one method, the intervertebral space I is prepared to receive the replacement disc nucleus 5300 through a first access device, and the replacement disc nucleus 5300 is inserted from the other side of the spine using a second access device. In various applications, one or more replacement disc nuclei 5300 may be delivered through one or more access devices, such as the access device 5304, from different approaches. Any combination of single, multiple replacement disc nuclei, or replacement disc nucleus sub-components may be delivered through one or more access devices from any combination of one or more approaches, such as the approaches shown in **FIGURE 90**, or any other suitable approach.

[0406] **FIGURE 91** shows a lateral view of a portion of a spine of a patient with the access device 5304 delivered thereto prior to treatment of the patient's natural disc. Advantageously, the access device 5304 may be configured so that when in the expanded configuration, the distal end 5316 does not extend beyond the locations of a nerve root 5352 or the spinal cord. The nerve root 5352 and the spinal cord are located outside the surgical space defined generally within the perimeter of the distal end 5316, and therefore are shielded from any implement or replacement disc nucleus or portion thereof delivered to the surgical location through the access device 5304. When in position, in addition to providing access to the interbody space I and the disc material therein, the distal portion 5324 may retract and shield the nerve root 5352 and spinal cord, and thereby protect the nerve root 5324 and spinal cord. The term "shield" as used in this context refers to the distal end 5316 of the access device 5304 being located between the surgical space and the nerve root 4352 or the spinal cord, or in contact with the nerve root 5352 or the spinal cord without applying significant force, e.g., tension or displacement force, to the nerve root 5352 or the spinal cord.

[0407] As shown in **FIGURE 75**, in some methods, suitable procedures may be performed to prepare the intervertebral space I to receive a replacement disc nucleus, e.g., the replacement disc nucleus 5300. First, a procedure may be performed whereby an aperture in the annulus fibrosus A is formed, e.g., an annulotomy procedure, through the access device 5304. Such a procedure may necessitate the deployment of additional surgical tools through the access device 5304. For example, an annulotomy may be performed using a trephine, and/or a knife, and / or one or more kerrisons. Other cutting instruments as well as non-cutting instruments may also be used to perform the annulotomy, e.g., lasers, RF, and other means well known to those of skill in the art. The aperture formed by these procedures provides access to the intervetebral space I beyond the annulus fibrosus A.

[0408] Once access to the intervertebral space I beyond the annulus fibrosus A has been provided, a disc evacuation tool 5356 may be inserted through the access device 5304 and used to remove at least a portion of the natural nucleus pulposus, and other disc material, as needed, through the access device 5304. The disc evacuation tool 5356 may comprise a shaver blade, RF device, laser, water jet or any other suitable instrument (e.g., a rongeur). In one preferred embodiment, the disc evacuation tool 5356 may be similar in construction and functionality to the steerable surgical instrument described in further detail below, in connection with FIGURES 116-118. Further advantages and features of such instruments are discussed above in connection with the disc replacement procedures. Additional surgical tools may also be deployed through the access device 5304 as needed. Tools used in connection with the access device 5304 or other access devices described herein, such as the disc evacuation tool 5356, preferably are generally elongated such that when the tools are applied to a patient during a surgical procedure through the access device 5304, a distal portion of the tool can be positioned through the aperture in the annulus fibrosus A, into the intervertebral space I. When so applied, a proximal portion of the tools preferably extends proximally of the proximal end 5312 of the access device 5304.

[0409] In some methods, all of the natural nucleus material is removed, e.g., where it will serve no further purpose or will detract from the performance of the replacement disc nucleus 5300. In other methods, there may be no need to perform an annulotomy or to remove pre-existing nucleus pulposus. For example, disc degeneration may have produced a hole in the annulus fibrosus A through which the natural nucleus has been ejected, e.g., a disc herniation. Any of the foregoing procedures to prepare the intervertebral space I may be performed though the access device 5304, inserted as shown, or through any other access device described herein or through a second access device described herein which has been inserted through any suitable approach.

[0410] **FIGURES 93-94** illustrate methods of applying replacement disc nuclei 5300 through the access device 5304. In particular, in **FIGURE 93**, after the access device 5304 is actuated to the expanded configuration, a disc nucleus 5300 that is at least partially injectable is delivered through the access device 5304, through an aperture in the annulus fibrosus A and into the intervertebral space I. Disc nuclei

that are at least partially injectable are illustrated in connection with **FIGURES 83 and 88**. In one application, though not shown in this **FIGURE 93**, in order to facilitate insertion of the replacement disc nucleus 5300, visualization of the surgical location may be achieved in any suitable manner, e.g., by use of a viewing element 5332, as discussed above.

[0411] In one procedure, a passage or conduit 5360 may be inserted through the access device 5304, through the aperture in the annulus fibrosus A and into the intervertebral space I. The conduit 5360 preferably has a hollow, elongate body that extends between a proximal end 5364 and a distal end 5368. The length of the elongate body is selected such that when the passage 5360 is applied to a patient during a surgical procedure, the distal end 5368 can be positioned through the aperture in the annulus fibrosus A, into the intervertebral space I, and, when so applied, the proximal end 5364 extends proximally to the proximal end 5312 of the access device 5304. In one embodiment, the passage or conduit 5356 facilitates the delivery of at least a portion of the disc nucleus 5300, e.g., a filler material or medium, as discussed above, into the intervertebral space I. In one embodiment, the filler material is injected into a pliable enclosure, as discussed above.

[0412] As shown in **FIGURE 93**, a container 5372 having the filler material of the injectable replacement disc nucleus 5300 remains external to the patient's body. The container may be attached to the proximal end 5364 of the passage 5360. As described above, the disc nucleus medium may comprise hydrogels, thermoplastic elastomers, proteinaceous biopolymers or other injectable materials. In one embodiment, the container 5372 may facilitate the injection of the disc nucleus medium through the passage 5360, through the aperture in the annulus A, into the intervertebral space I. In other embodiments, the injected medium may be pressurized to fill the intervertebral space I or to increase the disc height or volume. Different containers may be used, including a syringe.

[0413] In another application, the injectable replacement disc nucleus 5300 may be deployed by delivering the container 5372 through the access device 5304 into the intervertebral space I and then expelling its contents.

[0414] **FIGURE 94** illustrates further methods of delivering a replacement disc nucleus postero-laterally through the access device 5304a and through an aperture in the annulus fibrosus A into the intervertebral space I. In some applications, in order to facilitate insertion of the replacement disc nucleus 5300, visualization of the surgical location may be achieved in any suitable manner, e.g., by use of a viewing element 5332, as discussed above.

[0415] In one procedure, a gripping apparatus 5376 is coupled with one or more portions and/or surfaces of a replacement disc nucleus 5378 to facilitate insertion of the replacement disc nucleus. The gripping apparatus 5376 may be used in connection with replacement disc nuclei having solid form, e.g., as illustrated in connection with **FIGURES 84A – 87** and **FIGURE 89**. In one embodiment, the gripping apparatus 5376 is similar to the tool 2032, described above. The gripping apparatus 5376 has an elongate

body 5380 that extends between a proximal end 5384 and a distal end 5388. The length of the elongate body 5372 is selected such that when the gripping apparatus 5376 is inserted through the access device 5304a to intervertebral space I, the proximal end 5384 extends proximally of the proximal end 5312 of the access device 5304a. This arrangement permits the surgeon to manipulate the gripping apparatus 5376 proximally of the access device 5304a. The gripping apparatus 5376 has a grip portion 5392 that is configured to engage the replacement disc nucleus 5378.

[0416] In one embodiment, the grip portion 5392 comprises a clamping portion configured to firmly grasp opposing sides of the replacement disc nucleus 5378. The clamping portion may further comprise a release mechanism, which may be disposed at the proximal end 5384 of the gripping apparatus 5376, to loosen the clamping portion so that the replacement disc nucleus 5378 may be released once delivered to the intervertebral space I. In another embodiment, the grip portion 5392 comprises a jaw portion, such that a portion of the replacement disc nucleus 5378 fits within the jaw portion. In another embodiment, the grip portion 5392 comprises a malleable material that can conform to the shape of the replacement disc nucleus 5378 and thereby engage it. Other means of coupling the gripping apparatus 5376 to the replacement disc nucleus 5378 known to those of skill in the art could also be used, if configured to be inserted through the access device 5304a.

[0417] The replacement disc nucleus 5378 may be configured to be engaged by the grip portion 5392 of the gripping apparatus 5376. For example, the replacement disc nucleus 5378 could include a tab configured to be engaged by the grip portion 5392 of the gripping apparatus 5376. In one embodiment, the replacement disc nucleus 5378 is configured to fit within a jaw portion. In another embodiment, the replacement disc nucleus 5378 may be configured to fit within a clamping portion. In another embodiment, the replacement disc nucleus 5378 may be configured to mate closely with a corresponding surface in the grip portion 5392 of the gripping apparatus 5376.

[0418] In one method of delivering the replacement disc nucleus 5378 to the intervertebral space I, the gripping apparatus 5376 is coupled with the replacement disc nucleus 5378, as described above. The gripping apparatus 5376 and the replacement disc nucleus 5378 are advanced into the proximal end 5316 of the access device 5304, through the hole in the annulus fibrosus A, and further into the intervertebral space I, as indicated by an arrow 5394.

[0419] Once inserted, in some embodiments, the replacement disc nucleus 5378 may expand or swell to substantially fill the intervertebral space I e.g., in a manner similar to the replacement disc nucleus 5050, discussed above. In some procedures, the expansion or swelling of the disc nucleus 5378 may be encouraged or provided by a body fluid that hydrates and thereby enlarges the disc nucleus 5378 in situ. In other procedures, the disc nucleus 5378 is self-expanding to substantially fill the intervertebral space I. In still other procedures, external means may be used to expand or enlarge the disc nucleus 5378. These external means may include a device for injecting a liquid upon or within the disc nucleus 5378, e.g., a syringe, the

passage 5356 and container 5368 combination described above, or other means well known to those of skill in the art that might pass material through the access device 5300, through the aperture in the annulus fibrosus A, and into the intervertebral space I.

[0420] Although not shown in either **FIGURE 93** or **94**, any apertures formed in the annulus fibrosus A may be closed to prevent or minimize the escape or herniation of the replacement disc nuclei 5300, 5378, or similar replacement disc nuclei, or any portion thereof. Such a procedure may necessitate the deployment of additional surgical tools through any of the access devices described herein. For example, tools may be provided to stitch, suture, tape, plug or fill the void (e.g., to deliver a hydrogel plug), or otherwise repair the aperture in the annulus fibrosus A, either permanently or temporarily, may optionally be deployed. In some embodiments, artificial annulus fibrosus may be inserted through any of the access devices described herein and surgically attached to the natural annulus A to strengthen and reinforce the tissue.

[0421] Although the forgoing procedures are described in connection with a single level postero-lateral procedure, other procedures are possible. For example, multiple level nucleus replacement could be performed with one or more expandable conduit 20 or other suitable access device. As discussed above, other applications are also possible in which the access device 5304 is not expanded prior to delivery of the replacement disc nuclei 5300, 5378 or other similar nuclei. In such applications, the access device 5304 remains in the first configuration while the steps described above are performed, or a non-expandable access device may be provided. Also, other approaches could be adopted, e.g., anterior, posterior, transforaminal, or any other suitable approach. In one application, a replacement disc nucleus 5300, 5378 is inserted at the L5-S1 disc or at the L5-L4 disc anteriorly through the access device 5304.

[0422] As shown in **FIGURE 95**, a nucleus replacement procedure could also be combined with the insertion of a stabilization device between two adjacent vertebrae. The stabilization device may comprise a rigid system immobilizing the vertebrae V_1 and V_2 relative to each other, or may preserve motion between the vertebrae by means of a more dynamic system. Moreover, the access devices described herein may be used to perform all of these procedures, using single or multiple insertions. In one embodiment, a single access device is used first to replace a nucleus pulposus in an intervertebral space I with a replacement disc nucleus, and then to deliver and configure a stabilization device to the two vertebrae defining the intervertebral space I.

[0423] Although the methods discussed above are particularly directed to the insertion of a replacement disc nucleus, the apparatuses and systems described herein may also be used advantageously to extract or remove the replacement disc nuclei described herein, in a process known as revision. In one application, the means by which the aperture in the annulus A is closed may be configured to facilitate future annulotomies. Furthermore, any of the replacement disc nuclei may be configured to facilitate subsequent removal thereof. The gripping apparatus 5376 may also be further configured to facilitate removal as well as insertion. By providing minimally invasive access to the interbody space I, the access devices described

herein may be used analogously, as described above with reference to the removal of the natural nucleus pulposus, to remove a previously inserted replacement disc nucleus. In one application, the previously inserted replacement disc nucleus may then be replaced with a new replacement disc nucleus through the access devices described herein.

[0424] The foregoing methods and apparatuses advantageously provide minimally invasive treatment of disc conditions in a manner that preserves some degree of motion between the vertebrae on either side of a replaced nucleus. Accordingly, trauma to the patient may be reduced thereby, and recovery time shortened. As discussed above, many of the replacement disc nucleuses provide a more normal post-recovery range of motion of the spine, which can reduce the need for additional procedures.

C. Apparatuses, Systems and Methods for Preserving Vertebral Motion While Stabilizing the Spine

[0425] Another type of procedure that can be performed by way of the systems and apparatuses described hereinabove provides stabilization of skeletal portions, e.g. adjacent vertebrae in the spine, as would be the case in more conventional fixation procedures, but advantageously preserves a degree of normal motion. A variety of system and methods that may be used to provide motion preserving stabilization, such as dynamic stabilization, are described below. The access devices and systems described above enable these systems and methods to be practiced minimally invasively.

1. Stabilization Devices Allowing Axial Motion

[0426] A first type of motion preserving stabilization device is shown in **FIGURES 96-98**. In the illustrated embodiment, the motion preserving stabilization device 6000 is attached on the posterior side of the spine. However, the device 6000 may be modified for use on the anterior or lateral sides of the spine, or at locations between the anterior and lateral sides, or at locations between the lateral and posterior sides, e.g., at a posterolateral location. In one embodiment, the components of this stabilization device 6000 may be fabricated from a biocompatible metal, preferably titanium or a titanium alloy. The components may also be fabricated from other metals, or other suitable materials.

[0427] In one embodiment, the stabilization device 6000 comprises a plate 6004, a plurality of fasteners 6008, a plurality of fastener clamp portions 6012 and 6016, fastener spacers 6020, and stop locks 6024, as shown in **FIGURES 96-98**. The stabilization device 6000 and its components are further described in the following paragraphs.

[0428] In one embodiment, the plate 6004 is the framework upon which the other components are attached. In one embodiment, the plate 6004 is an elongate member having a caudal end and a cephalad end, and defining a longitudinal axis extending from the caudal end to the cephalad end. The plate 6004 may have a slot parallel to its longitudinal axis to receive and contain the fasteners 6008. The slot advantageously allows the fasteners 6008 to be infinitely positioned axially to place it into the desired position relative to the vertebra. The plate optionally may be formed from a single piece of metal. Another approach would be to provide preformed holes, which would limit the location of the fasteners 6008 with respect to the plate 6004.

The plate 6004 may be curved or otherwise shaped or configured to allow for stabilizing a spine or positioning individual vertebrae as required. Although not shown, the plate 6004 may have one or more open ends. The open ends can enable different fastener elements to be more easily inserted, and may then be closed and stiffened with one or more stop locks 6024. In another embodiment, the slot need not extend the entire length of the plate 6004, but can provide a more limited range of potential axial positions. In another embodiment, the plate 6004 may have a more rod-like shape with a hollowed out portion adapted to engage a portion of the fasteners 6008. In another embodiment, the plate 6004 may incorporate a hinge by which it is attached to at least one fastener 6008, such that the at least one fastener 6008 can move with respect to at least one other fastener 6008.

[0429] In **FIGURE 97**, a partial cross-sectional view of one embodiment of the fastener 6008 is shown. The fastener 6008 may comprise a bone screw, such as a conventional pedicle screw similar to the fastener 600 described above. The fastener has tapered screw threads 6028 at a bone end 6032, a head which will accept a tool near a midsection 6036, and a machine screw threaded stud 6040 at a clamp end. In other embodiments, in place of a bone screw, other fastener means, such as straight pins or tapered pins, bone hooks, or others, may be used to provide attachment with the bone. In one embodiment, the fastener may also have a screwdriver slot to adjust the screw height as shown in **FIGURE 98**.

[0430] In one embodiment, the fastener 6008 is attached to the plate 6004 via the fastener clamp portions 6012 and 6016, shown in **FIGURE 98** and more clearly in the detailed view shown in **FIGURE 98**. In one embodiment, a nut 6044 clamps the upper fastener clamp portion 6012, through the plate 6004, to the lower fastener clamp portion 6016, and against a collar 6048 on the fastener 6008 to give metal-to-metal clamping. Because of the metal-to-metal clamping, the fastener 6008 does not require anti-rotational locks such as auxiliary screw clamps, cams, wedges or locking caps. The metal-to-metal clamping of the fastener 6008 to the plate 6004 provides a fully rigid bone stabilizer system. In other embodiments, other means of attaching the plate 6004 to the fasteners 6008 may be used. The fastener clamp portions 6012 and 6016 may be machined to angular shapes to allow the fastener 6008 to be attached to the plate 6004 at different angles.

[0431] In one application, spacers 6020 are selectively installed between the fastener clamp portions 6012 and 6016 to allow axial motion of the fasteners 6008 along the slot with respect to the plate 6004. This spacer 6020 installation may preserve motion between the fasteners 6008 and the plate 6004. A spacer 6020 is a piece of material with a width greater than the width of the plate 6004 placed between the fastener clamp portions 6012 and 6016, such that the fastener clamp portions 6012 and 6016 fixedly contact the spacer 6020 and not the plate 6004. In one embodiment, because of the metal-to-metal clamping through the spacer 6020, auxiliary screw clamps such as a cam, a wedge or a locking cap may not be needed. To reduce the number of small parts, the lower fastener clamp portion 6016 and the spacer 6020 may optionally

be fabricated as one integral part. If desired, in a rigid installation without a spacer 6020, the nut 6044 may force the fastener clamp portions 6012 and 6016 directly against the plate 6004.

[0432] In one embodiment, the stop locks 6024 may be clamped to the plate 6004 to maintain plate rigidity, and they may serve as travel limit stops to preserve or to favor motion in one direction and to limit or eliminate it in the opposite direction. This action is sometimes referred to herein as unidirectional, dynamized action of the fasteners 6008 with respect to the plate 6004. In one embodiment, the motion of the fasteners 6008 in a cephcaudal direction is limited. In one embodiment, the stop lock 6024 includes an upper portion, a lower portion, and a screw, which assembly can be attached to the plate 6004 in a similar manner to the fastener clamp portions 6012 and 6016 described above. The stop locks 6024 may be preloaded before tightening the stop lock screw. The stop locks 6024 may also utilize springs or other force generating means to maintain compression on the vertebra/graft interface.

[0433] **FIGURE 96** shows that two stabilization devices 6000 can be used in conjunction on either side of the spinous processes, extending across three vertebrae. The stabilization device 6000 may alternatively be applied with one or more plates, and they may extend across two or more vertebrae.

[0434] In one embodiment, the unidirectional, dynamized action between the fasteners 6008 and plate 6004 preserves subsidence of the vertebrae, motion of an upper vertebra in a caudal direction. Among other advantages, this allows for graft resorption and settling. It also provides improved fusion conditions and prevents graft distraction. The stabilization device 6000 can also provide stress shielding to the stabilized vertebrae along other directions, including: rotation causing axial shear; lateral bending causing contralateral distraction; flexion causing posterior distraction; extension causing anterior distraction; horizontal force causing translation shear; and extension causing distraction.

[0435] Further details of structures that provide support and stability while preserving motion may be found in U.S. Patent Application No. 09/846,956 filed on May 1, 2001, published as U.S. Patent Application No. 2001/0037111 on November 1, 2001, which is hereby incorporated by reference in its entirety.

[0436] **FIGURE 41** shows another, similar embodiment of a motion preserving stabilization device 6100, which includes rods 6104, 6108 interconnected by a pair of plates 6112, 6116 each secured to a respective vertebra by multiple fasteners. In one embodiment, although the **FIGURE** shows an anterior insertion, the stabilization device 6100 is configured to be secured to the posterior side of the spine. The device 6100 may also be modified for use on the anterior or lateral sides of the spine, or at a location between the anterior and lateral sides, or at a location between the lateral and posterior sides, e.g., posterolateral.

[0437] In one embodiment, the stabilization device 6100 comprises a pair of surgically implantable rods 6104 and 6108. The stabilization device 6100 may also include first and second plates 6112 and 6116, which engage the rods 6104 and 6108; three fasteners 6120, 6124, and 6128 for connecting the first plate 6112 with the first vertebra V1; and three fasteners 6132, 6136, and 6140 for connecting the second plate 6116 with the second vertebra V2.

[0438] The first rod 6104 is made of a suitable biocompatible material, such as titanium or stainless steel. In one embodiment, the first rod 6104 has an elongate cylindrical configuration and has a circular cross section taken in a plane extending perpendicular to the longitudinal central axis of the first rod. The first rod 6104 may also have a smooth outer surface. A first end portion of the first rod 6104 may comprise a cap 6144. The first rod 6104 may also have a second end portion 6148 opposite from the cap 6144. In one embodiment, the rod 6104 has a uniform diameter of about three (3) millimeters throughout its extent except at the cap 6144.

[0439] The second rod 6108 may be substantially identical to the first rod 6104. In one embodiment, the second rod 6108 has a first end portion comprising a cap 6152. The second rod 14 may also have a second end portion 6156 opposite from the cap 6152. In one embodiment, the rods 6104 and 6108 are bendable to a desired configuration to conform to a desired curvature of the spinal column. In a preferred embodiment, the rods 6104 and 6108 together have sufficient strength and rigidity to maintain the vertebrae V1 and V2 in a desired spatial relationship.

[0440] In one embodiment, the rods 6104 and 6108 have a length sufficient to enable them to span at least the two vertebrae V1 and V2. The length of the rods 6104 and 6108 will depend upon the condition to be corrected and the number of vertebrae to be held in a desired spatial relationship relative to each other by the stabilization device 1100. If more than two vertebrae are to be held in a desired spatial relationship relative to each other by the stabilization device 6100, the rods 6104 and 6108 could be longer, and more than two plates, such as the plates 6112 and 6116, may be used.

[0441] The first plate 6112 may be made of any suitable biocompatible material, such as titanium or stainless steel. In one embodiment, the first plate 6112 includes a main body portion. The main body portion of the first plate 6112 may have a planar outer side surface for facing away from the first vertebra V1. The first plate 6112 may have an arcuate inner side surface for facing toward the first vertebra V1. The inner side surface of the first plate 6112 may engage the surface of the first vertebra V1 when the first plate is connected with the first vertebra as described below.

[0442] The main body portion of the first plate 6112 may also have a central portion which extends laterally between a first side portion 6160 and a second side portion 6164 of the first plate 6112. Because the inner side surface of the first plate 6112 has an arcuate configuration, the central portion of the first plate 6112 may be relatively thin as compared to the first side portion 1160 and to the second side portion 6164.

[0443] In one embodiment, the main body portion of the first plate 6112 also has first and second end portions 6168 and 6172. The first end portion 1168 of the first plate 6112 may include a planar first end surface of the first plate 6112. The second end portion 6172 may include a planar second end surface of the first plate 6112. The second end surface may extend parallel to the first end surface.

[0444] In one embodiment, a first rod passage is formed in the first side portion 6160 of the first plate 6112. The first rod passage is an opening that extends between the first and second end surfaces of the first plate 6112, in a direction parallel to the planar outer side surface of the first plate 6112. The first rod passage may be defined by a cylindrical surface and tapered pilot surfaces and at opposite ends of the cylindrical surface. The diameter of the cylindrical surface is optionally slightly greater than the diameter of the first rod 6104, so that the first rod 6104 and the first plate 6112 can be relatively movable.

[0445] In one embodiment, the second side portion 6164 of the first plate 6112 is a mirror image of the first side portion 6160. A second rod passage is formed in the second side portion 6164 of the first plate 6112. The second rod passage is an opening that extends between the first and second end surfaces of the first plate 6112, in a direction parallel to the planar outer side surface of the first plate 6112. The second rod passage extends parallel to the first rod passage. In one embodiment, the second rod passage is defined by a cylindrical surface and tapered pilot surfaces at opposite ends of the cylindrical surface. The diameter of the second rod passage is preferably the same as the diameter of the first rod passage. The diameter of the cylindrical surface is optionally slightly greater than the diameter of the second rod 6108, so that the second rod 6108 and the first plate 6112 can be relatively movable.

[0446] In one embodiment, a circular first fastener opening extends through the central portion of the first plate 6112. The first fastener opening has an axis that extends perpendicular to the plane of the outer side surface of the first plate 6112. The first fastener opening may be partially defined by a larger diameter cylindrical surface, which extends from the outer side surface of the first plate 6112 in a direction into the material of the central portion of the first plate 6112. The cylindrical surface is centered on the axis of the first fastener opening. The first fastener opening may also be partially defined by a smaller diameter cylindrical surface, which extends from the inner side surface of the first plate 6112 in a direction into the material of the central portion of the first plate to a location spaced radially inward from the larger diameter cylindrical surface. This smaller diameter cylindrical surface may also be centered on the axis of the first fastener opening 90.

[0447] In one embodiment, an annular shoulder surface extends radially (relative to the axis of the first fastener opening 90) between the larger and smaller diameter cylindrical surfaces. The shoulder surface and the larger diameter cylindrical surface define a recess in the outer side surface of the first plate 6112.

[0448] The main body portion of the first plate 6112 may also include a circular second fastener opening formed at a location adjacent to, but spaced apart from, the first rod passage in the first side portion 6160 of the first plate 6112. The second fastener opening may extend through both the second end surface of the first plate 6112 and the outer side surface of the first plate 6112. In one embodiment, the second fastener opening is partially defined by a larger diameter cylindrical surface, a smaller diameter

cylindrical surface and an annular shoulder surface, in a configuration similar to that of the first fastener opening.

[0449] The main body portion of the first plate 6112 may also include a circular third fastener opening formed at a location adjacent to, but spaced apart from, the second rod passage in the second side portion 1164 of the first plate 6112. The third fastener opening may extend through both the second end surface of the first plate 6112 and the outer side surface of the first plate 6112. In one embodiment, the third fastener opening is partially defined by a larger diameter cylindrical surface, a smaller diameter cylindrical surface and an annular shoulder surface, in a configuration similar to that of the first fastener opening.

[0450] The second plate 6116 may be generally similar in configuration to the first plate 6112, with rod passages disposed on both sides. The second plate 6116 may be configured, however, so that the head ends of the fasteners 6136, 6140 received in certain fastener openings in the second plate 6116 are engageable with the rods 6104 and 6108 disposed in rod passages in the second plate 6116. This engagement can block movement of the second plate 6116 relative to the rods 6104 and 6108, in a manner described below.

[0451] One or both of the fastener openings receiving the fasteners 6136 or 6140 may be partially defined by a larger diameter cylindrical surface which extends from the outer side surface of the second plate 6116 in a direction into the material of the first side portion of the second plate. This larger diameter cylindrical surface is centered on an axis of the fastener opening. The larger diameter cylindrical surface may also intersect the cylindrical surface that defines a rod passage in the second plate 6116. Thus, the fastener opening overlaps a portion of a rod passage.

[0452] In one embodiment, the fasteners 6120, 6124, 1128, 6132, 6136, and 6140, which connect the first plate 6112 with the first vertebra V1, and the second plate 6116 with the second vertebra V2, may be identical to each other. These fasteners 6120, 6124, 1128, 6132, 6136, 6140 may comprise bone screws, such as conventional pedicle screws similar to the fastener 600 described above. In other embodiments, in place of a bone screw, other fastener means, such as straight pins or tapered pins, bone hooks, or others, may be used to provide attachment with the bone.

[0453] When the second plate 6116 is connected with the second vertebra V2, the fasteners 6132, 6136 and 6140 secure the second plate and the second vertebra. The outer fasteners 6136 and 6140 may also serve to interlock the second plate 6116 with the rods 6104 and 6108, by moving into engagement with the rods 6104 and 6108, respectively, when each fastener is fully screwed into a respective vertebra. In one embodiment, the engagement between the fasteners 6136 and 6140 and the rods 6104 and 6108 blocks movement of the fasteners 6136 and 6140 relative to the rods. As a result, the fasteners 6136 and 6140 may also block movement of the second plate 6116 relative to the rods 6104 and 6108. Other means of blocking the movement of the second plate 6115 relative to the rods 6104 and 6108 are well known to those of skill in the art.

[0454] In one embodiment, the first plate 6112, in contrast, preserves motion relative to the rods 6104 and 6108, because the second and third fastener openings are spaced apart from the first plate's rod passages. In a preferred embodiment, the first plate 6112 is thus movable relative to the second plate 6116. In other embodiments, this motion preserving stabilization system 6100 may consist of two or more movable plates like 6112, with no fixed plates like 6116.

[0455] Accordingly, the first vertebra V1 may be movable vertically downward relative to the second vertebra V2. This relative movement allows for the maintaining of a load on bone graft placed between the vertebrae V1 and V2. If the first plate 6112 were not movable vertically downward relative to the second plate 6116, then the distance between the vertebrae V1 and V2 would be fixed. If bone graft were placed between the vertebrae V1 and V2 and the bone graft resorbed sufficiently, the bone graft could possibly shrink out of engagement with one or both of the vertebrae V1 and V2. Allowing relative movement of the plates 6112 and 6116 can help to maintain a load on bone graft placed between the vertebrae V1 and V2 and maintains the vertebrae in contact with the bone graft to facilitate bone growth.

[0456] The caps 6144 and 6152 on the rods 6104 and 6108, respectively, limit movement of the first vertebra V1 in a direction away from the second vertebra V2. This helps to maintain the vertebrae V1 and V2 in contact with the bone graft.

[0457] The stabilization device 6100 can also provide stress shielding to the stabilized vertebrae along other directions, including: rotation causing axial shear; lateral bending causing contralateral distraction; flexion causing posterior distraction; extension causing anterior distraction; horizontal force causing translation shear; and extension causing distraction.

[0458] Further details of structures that provide support and stability while preserving motion may be found in U.S. Patent No. 6,036,693 filed on November 30, 1998, which is hereby incorporated by reference in its entirety.

2. Stabilization Device Having a Flexible Elongate Member

[0459] **FIGURE 100** shows another embodiment of a motion preserving stabilization device 6200 extending across five vertebrae. As discussed more fully below, multiple stabilization devices 6200 may be applied to a spine in parallel, and may extend across more or fewer vertebrae. The stabilization device 6200 includes an elongate member 6204 secured to a plurality of fasteners 6208. In one embodiment, each fastener 6208 is engaged to a respective one of the vertebrae V1, V2, V3, V4, V5. A coupling member 6212 is engaged to each of the fasteners 6208 with the elongate member 6204 positioned between each fastener 6208 and its respective coupling member 6212.

[0460] It should be understood that the stabilization device 6200 may be utilized in all regions of the spine, including the cervical, thoracic, lumbar, lumbo-sacral and sacral regions of the spine. Additionally, although the stabilization device 6200 is shown in **FIGURE 100** as having application in a posterior region of the spine, it may alternatively be applied in other surgical approaches and combinations of

surgical approaches to the spine such that one or more stabilization devices 6200 are attached to the anterior, antero-lateral, lateral, and/or postero-lateral portions of the spine.

[0461] In one embodiment, the stabilization device 6200 allows at least small degrees of spinal motion between the vertebrae to which it is attached, since the stabilization device 6200 includes an elongate member 6204 that is at least partially flexible between adjacent fasteners 6208. It should be understood that the stabilization device 6200 can be used in conjunction with fusion or non-fusion treatment of the spine. In one embodiment, the elongate member 6204 is a tether made from one or polymers, such as, for example, polyester or polyethylene; one or more superelastic metals or alloys, such as, for example, nitinol; or from resorbable synthetic materials, such as, for example suture material or polylactic acid. It is further contemplated that the elongate member 6204 may have elasticity such that when tensioned it will tend to return toward its pre-tensioned state. In other embodiments, the shape and size of the elongate member 6204 can be modified to adjust its elasticity and flexibility along different axes.

[0462] The fasteners 6208 and coupling members 6212 described herein may be employed with the shown stabilization device 6200. In addition, it is contemplated that the fasteners 6208 and coupling members 6212 described herein may be employed in isolation or in devices that include two or more coupling members 6212 and fasteners 6208. Examples of other devices include: one or more elongate members 6204 extending laterally across a vertebral body; one or more elongate members 6204 extending in the anterior-posterior directions across a vertebral body; one or more elongate members 6204 wrapped around a vertebral body; and combinations thereof. Further examples include application of the fasteners 6208 and coupling members 6212 of the present invention with bony structures in regions other than the spinal column.

[0463] In one embodiment, a fastener 6208 may comprise a bone screw, such as a conventional pedicle screw similar to the fastener 600 described above. In other embodiments, in place of a bone screw, other fastener means, such as straight pins or tapered pins, bone hooks, or others, may be used to provide attachment with the bone. Similarly, a coupling member 6212 may comprise a cap screw similar to the cap screw 610 described above. In another embodiment, the coupling member 6212 comprises a threadable portion to threadably engage the fastener 6208, and a penetrating element to penetrate the elongate member 6204. In other embodiments, the coupling member 6212 may comprise another means of engaging a fastener 6208 and the elongate member 6204.

[0464] The motion preserving elongate member 6204 of this stabilization device 6200 enables adjacent vertebrae to move relative to each other depending on the elongate member's 6204 flexibility, while partially reproducing the restorative forces of a healthy spine. Moreover, the stabilization device 6200 may be stiffer along the direction of the longitudinal axis, reducing the compressive forces imposed upon the intervertebral regions, and providing support for the spine's load-bearing functions.

[0465] Further details of structures that provide support and stability while preserving motion may be found in U.S. Patent Application No. 10/013,053 filed on Oct. 30, 2001, published as U.S. Patent

Publication No. 2003/0083657 on May 1, 2003, and U.S. Patent Application No. 09/960,770 filed on Sep. 21, 2001, published as U.S. Patent Publication No. 2002/0013586 on January 31, 2002, which are hereby incorporated by reference in their entirety.

3. Stabilization Device with a Jointed Link Rod

[0466] **FIGURE 101** illustrates a portion of another embodiment of a stabilization device 6250. In one embodiment, the stabilization device 6250 is configured to be secured to the posterior side of the spine. However, the device 6250 may be modified for use on the anterior or lateral sides of the spine, or at a location between the anterior and lateral sides, or at a location between the lateral and posterior sides, e.g., posterolateral.

[0467] In the example shown in **FIGURE 101**, a set of fasteners connected to at least two vertebrae may be interconnected by a link rod 6254 comprising at least two rigid segments 6254A and 6254B, which are interconnected by means of a damper element 6258 interposed between their facing free ends, so as to oppose elastic resistance between the segments 6254A and 6254B with amplitude that may be controlled not only in axial compression and traction a, but also in angular bending b.

[0468] A single link rod 6254 may include a plurality of dampers 6258 disposed between the vertebrae. Also, the link rod 6254 may advantageously be cut to a selected length and curved to a selected radius.

[0469] As can be seen more clearly in **FIGURE 101**, the damper element 6258 may be made up of two elastically deformable members 6258A disposed around the free end of a pin 6254Ba extending from one of the segments 6254B constituting the rod 6254. The pin 6254Ba may be engaged inside a housing 6262a formed in a blind sleeve or cage 6262 made at the free end 6254Aa of the other link segment 6254A. In one embodiment, the damper element 6258 comprises a rigid piston 6266 formed on the pin 6254Ba to constitute a joint 6266 making multidirectional relative pivoting possible between the cage 6262 and the pin 6254Ba, at least about axes contained in a plane perpendicular to the longitudinal axis x-x' of the damper element 6258 when the pin 6254Ba and the cage 6262 are in alignment.

[0470] In one embodiment, the resulting joint 6266 is of the ball-and-socket type that also allows the cage 6262 to rotate relative to the pin 6254Ba about the axis x-x'. The joint 6266 may comprise a collar projecting radially from the pin 6254Ba and having an outside surface with a rounded profile that is designed to come into contact with the inside surface of the housing 6262a in the cage 6262. In the embodiment shown in **FIGURE 101**, the collar 6266 is an integral part of the pin 6254Ba, although in other examples, the collar 6266 may comprise a separate ring that is fixed on the pin 6254Ba.

[0471] The collar 6266 is disposed relative to the pin 6254Ba in such a manner as to receive thrust on both of its lateral faces from two sets of spring washers 6270 each in the form of a pair of facing frustoconical cups of identical diameter stacked on the pin 6254Ba. The washers 6270 and the joint 6266 occupy at least part of the circular section housing 6262a, whose end wall constitutes a compression abutment for one of the elastically deformable members 6258A. It should be observed that the spring

washers 6270, which are also known as "Belleville" washers, can be replaced by other spring-like elements, such as elastomer rings.

[0472] In one embodiment, the housing 6262a of the cage 6262 is closed by a first washer 6274 secured to the cage 6262 and having an inside face against which there bears a second washer 6278 secured to the pin 6254Ba. The deformable members 6258A may be placed freely on the pin 6254Ba between the second washer 6278 and the end wall of the housing 6262a. For example, the first washer 6274, which constitutes an axial abutment, can be implemented in the form of a threaded ring screwed into tapping made inside the housing from its outer end, thereby making it possible to adjust the extension position of the damper. It should be observed that the second washer 6278, which is secured to the pin 6254Ba, constitutes a bearing surface for an elastically deformable member 6258A. This second washer 6278 can serve as an abutment for the damper in axial traction. This second washer 6278 thus makes it possible to exert compression force on the deformable member without damaging it. In addition, according to an advantageous characteristic, the second washer 6278 can be made of a material that is identical to that constituting the elastically deformable member, so as to make it possible to control the friction which appears between the second washer 6278 and the elastically deformable member 6258A.

[0473] The elastically deformable members 6258A are maintained with axial clearance that makes it possible, when they deform elastically, to accommodate relative axial movements in compression and traction between the pin 6254Ba and the cage 6262. For example, it is possible to obtain axial compression or traction having a value of 0.8 mm. In addition, the elastically deformable members 6258A may be mounted to allow multidirectional relative pivoting between the pin 6254Ba and the cage 6262. The washers 6270 may therefore be mounted inside the housing 6262a with clearance relative to the inside wall of the housing.

[0474] In one embodiment, the damper element 6258 includes an angular abutment for limiting the multidirectional relative pivoting to a determined value having an amplitude of about 4 degrees. Thus, as can be seen more clearly in **FIGURE 101**, the displacement b of the pin 6254Ba in the cage 6262 relative to its normal, aligned position is 2 degrees. In the embodiment shown, the angular abutment is provided by the housing 6262a against which the pin 6254Ba comes into abutment, which pin 6254Ba has a predetermined amount of radial clearance relative to the housing 6262a to enable relative pivoting to take place through the predetermined angle b. Thus, the pin 6254Ba presents radial clearance both between its collar 6266 and the housing 6262a, and between its free end and a blind recess 6262b extending the housing 6262a. Relative pivoting between the cage 6262 and the pin 6254Ba is thus limited by implementing two angular abutments defined by the co-operation firstly between the collar 6266 and the housing 6262a, and secondly between the free end of the pin 6254Ba and the blind recess 6262b. It should be observed that the two abutments constituted in this way are set up in opposition about the axis x-x'. This allows limited bending to be obtained between the cage and the pin in all directions of angular displacement.

[0475] This motion preserving link rod 6254 of this stabilization device 6250 enables adjacent vertebrae to move relative to each other depending on the flexibility of the incorporated joint 6266, while partially reproducing the restorative forces of a healthy spine. Moreover, the stabilization device 6250 may be stiffer along the direction of the longitudinal axis, reducing the compressive forces imposed upon the intervertebral regions, and providing support for the spine's load-bearing functions.

[0476] Further details of structures that provide support and stability while preserving motion may be found in U.S. Patent No. 6,241,730 filed on November 27, 1998, which is hereby incorporated by reference in its entirety.

4. Stabilization Device with a Spring Element

[0477] **FIGURE 44** illustrates another embodiment of a stabilization device 6300. In one embodiment, the stabilization device 6300 is configured to be secured to the posterior side of the spine. However, the device 6300 may be modified for use on the anterior or lateral sides of the spine, or at a location between the anterior and lateral sides, or at a location between the lateral and posterior sides, e.g., posterolateral.

[0478] In one embodiment, the body 6304 of the stabilization device 6300 comprises a leaf spring 6308 in the form of a closed loop and in one piece with fasteners 6312. The stabilization device 6300 is preferably made of titanium or titanium alloy, although other biocompatible materials may be used. In one embodiment, the spring 6308 defines two leaf spring parts 6308a, 6308b extending parallel to each other in the alignment direction 6316. The generatrix 6320 extends from front to rear, and defines the moving straight line, whose path defines the planar leaf spring 6308 of the stabilization device 1300.

[0479] The two parts 6308a, 6308b of the spring may be symmetrical to each other with respect to a median plane passing through the axis 6316. Each spring part forms a plurality of successive U-shapes alternately oriented in opposite directions in a plane perpendicular to the generatrix 6320. In one embodiment, each part 6308a, 6308b has three of these U-shapes. The U-shapes nearest the fasteners 6312 have their base facing towards the outside of the stabilizing device 6300, and the middle U-shape of each part has its base facing towards the inside of the stabilizing device 1300. Each part 6308a, 6308b therefore forms an undulation or zig-zag. To be more precise, the general shape of this embodiment is that of an inverted M.

[0480] In one embodiment, each fastener 6312 comprises two jaws 6328, which are symmetrical to each other with respect to the median plane, generally flat in shape and have a generatrix parallel to the generatrix 6320. The two jaws 6328 face each other. Their facing faces have profiled teeth 6332. Each jaw has a passage 6336 for inserting a tool for maneuvering the jaw and whose axis is parallel to the generatrix 6320. The bases of the jaws 6328 extend at a distance from each other from one end of the spring 6308. The two jaws 6328 are mobile elastically relative to each other. At rest they diverge from their base.

[0481] To fit the stabilizing device 6300, the jaws 6328 of each fastener 6312 may be forced apart using tools inserted into the passages 6336. The stabilizing device 6300 may then be placed as shown in **FIGURE 102** so that each spinous process 6340 is between the respective jaws 6328. The jaws are then released so that they grip the processes and are anchored to them by their teeth 6332.

[0482] The leaf spring parts 6308a, 6308b may extend laterally beyond the spinous processes 6340. They can be configured to impart a low stiffness to them. A stabilizing device 6300 may optionally be fabricated by spark erosion from a mass of metal; this fabrication process being particularly simple because of the profile of the device 6300. In one embodiment, this stabilizing device 6300 has a relatively low stiffness for lateral flexing of the body, i.e. flexing about an axis parallel to the generatrix 6320. It has a high stiffness for flexing of the body from front to rear, i.e. flexing about an axis perpendicular to the direction 6316 and to the generatrix 6320. In other embodiments, the shape of the spring 6308 can easily be modified to increase or reduce at least one of the stiffnesses referred to above, independently of the volume available between the processes 6340.

[0483] Although the spring element 6308 resists deformation proportionally to an effective spring constant, its structure also preserves some amount of motion between adjacent vertebrae. In one embodiment, the spring 6308 may be configured to allow some proportion of the axial forces to be imposed upon the intervertebral region, while providing restorative forces. This motion preserving device thereby facilitates healing and shields the spine from some postoperative stress.

[0484] Further details of structures that provide support and stability while preserving motion may be found in U.S. Patent No. 6,440,169 filed on January 27, 1999, which is hereby incorporated by reference in its entirety.

5. Stabilization Device Made From Flexible Material

[0485] **FIGURE 103** illustrates another embodiment of a stabilization device 6350. In one embodiment, the stabilization device 6350 is configured to be secured to the posterior side of the spine. However, the device 6350 may be modified for use on the anterior or lateral sides of the spine, or at a location between the anterior and lateral sides, or at a location between the lateral and posterior sides, e.g., posterolateral.

[0486] In this embodiment of a stabilization device 6350, flexible implants 6354 are anchored to the adjacent vertebrae V1, V2 and V3. The implants 6354 preferably have a low profile and are conformable to the spinal anatomy to minimize intrusion into the surrounding tissue and vasculature. The implants 6354 attach to vertebrae and prevent separation of the vertebrae while allowing normal extension and articulation of the spinal column segment. Portions of the implants 6354 and the fasteners 6358 attaching the implant 6354 to vertebrae can be at least partially or fully embedded within the vertebrae to minimize intrusion into the surrounding tissue and vasculature.

[0487] It is contemplated that the flexible implants 6354 of the stabilization device 6350 described herein can be made from resorbable material, nonresorbable material and combinations thereof. In

one example, resorbable implants 6354 can be used with interbody fusion devices since a permanent exterior stabilization may not be desired after fusion of the vertebrae. It is also contemplated that the fasteners 6358 used to attach the implants 6354 to the vertebrae can be made from resorbable material, nonresorbable material, and combinations thereof.

[0488] The implants 6354 can be flexible, tear resistant, and/or suturable. The flexible implant 6354 can also be fabricated from synthetic flexible materials in the form of fabrics, non-woven structures, two or three dimensional woven structures, braided structures, and chained structures. The implants 6354 can also be fabricated from natural/biological materials, such as autograft or allograft, taken from patellar bone-tendon-bone, hamstring tendons, quadriceps tendons, or Achilles tendons, for example. Growth factors or cells can be incorporated into the implants 6354 for bone ingrowth and bony attachment or for soft tissue ingrowth. Possible growth factors that can be incorporated include transforming growth factor β1, insulin-like growth factor 1, platelet-derived growth factor, fibroblast growth factor, bone morphogenetic protein, LIM mineralization protein (LMP), and combinations thereof.

[0489] Possible implant materials include synthetic resorbable materials such as polylactide, polyglycolide, tyrosine-derived polycarbonate, polyanhydride, polyorthoester, polyphosphazene, calcium phosphate, hydroxyapatite, bioactive glass and combinations thereof. Possible implant materials also include natural resorbable materials such as autograft, allograft, xenograft, soft tissues, connective tissues, demineralized bone matrix, and combinations thereof. Possible implant material further include nonresorbable materials such as polyethylene, polyester, polyvinyl alcohol, polyacrylonitrile, polyamide, polytetrafluorethylene, poly-paraphenylene terephthalamide, cellulose, shape-memory alloys, titanium, titanium alloys, stainless steel, and combinations thereof.

[0490] The stabilization device 6350 described herein includes fasteners 6358 to attach the implant 6354 to the vertebrae. It is contemplated that the fasteners 6358 can be, for example, interference screws or anchors, gull anchors, suture anchors, pin fasteners, bone screws with spiked washers, staples, buttons, or bone screws such as the fastener 600 described above. It is contemplated that the fasteners 6358 can be made from resorbable materials, nonresorbable materials, and combinations thereof. Possible synthetic resorbable materials include polylactide, polyglycolide, tyrosine-derived polycarbonate, polyanhydride, polyorthoester, polyphosphazene, calcium phosphate, hydroxyapatite, bioactive glass, and combinations thereof. Possible natural resorbable materials include cortical bone, autograft, allograft, and xenograft. Possible nonresorbable materials include carbon-reinforced polymer composites, shape-memory alloys, titanium, titanium alloys, cobalt chrome alloys, stainless steel, and combinations thereof.

[0491] Referring now to **FIGURE 103**, the stabilization device 6350 includes a flexible implant 6354 that extends along the posterior faces of vertebrae V1, V2 and V3, and is attached to a first vertebra V1 and a second vertebra V3. The flexible implant 6354 may be configured to resist extension, flexion, and/or

lateral bending loads created by motion of the spinal column depending on the location or locations of the spinal column segment on which the implant 6354 is positioned.

[0492] In one embodiment, the flexible implant 6354 has a first end 6354a and an opposite second end 6354b. Vertebra V1 includes a first opening on its posterior face and a first tunnel extending therefrom. Vertebra V3 has a second opening on its posterior face and a second tunnel extending therefrom. The ends 6354a and 6354b are inserted into respective ones of the first and second tunnels through these openings. An fastener 6358a is also inserted through the opening in V1, and into the tunnel of vertebra V1 to secure end 6354a to vertebra V1. Similarly, an fastener 6358b is inserted through the opening in V3, and into the tunnel of vertebra V3 to secure end 6354b to vertebra V3. Fasteners 6358a, 6358b are illustrated as threaded interference screws that are embedded into vertebral bodies V1 and V3 so that they do not protrude from the posterior faces of vertebrae V1 and V2. However, other fasteners and fastening techniques described herein could also be employed with implant 6354.

[0493] In one embodiment, the fasteners 6358a, 6358b can be oriented at an angle, alpha, with respect to the axial plane of the spinal column, in order to provide a smooth transition for implant 6354 as it enters the openings of the vertebrae V1 and V3. This reduces stress concentrations at the junction between the implant 6354 and the vertebrae. In one embodiment, angle, alpha, is about 45 degrees. Other embodiments contemplate angular orientations that range from 0 degrees to about 80 degrees and from about 25 degrees to 65 degrees.

[0494] The ends of implant 6354 and other possible implants can be provided with pigtails or other extensions of reduced size for insertion through the openings and tunnels formed in the vertebrae. It is also contemplated that the ends of the implant can include eyelets, holes, loops or other configuration suitable for engagement with an anchor. In another embodiment (not shown), the implant 6354 comprises a broad swath of material through which the fasteners 1358 are advanced to provide attachment to the underlying vertebrae.

[0495] In **FIGURE 103**, two stabilization devices 6350 are shown extending across three vertebrae. It is further contemplated that more or fewer stabilization devices 6350 may be applied to a spine in parallel, and may extend across more or fewer vertebrae.

[0496] While the implants 6354 do not provide stress shielding against compressive loading, they do provide stabilization by resisting extension, lateral bending, and rotation. Thus, this stabilization device provides some stabilization while preserving motion between the vertebrae. Further details of structures that provide support and stability while preserving motion may be found in U.S. Patent Application No. 10/078,522 filed on Feb. 19, 2002, published as U.S. Patent Publication No. 2002/0120269 on August 29, 2002, and U.S. Patent Application No. 10/083,199 filed on Feb. 26, 2002, published as U.S. Patent Publication No. 2002/0120270 on August 29, 2002, which are hereby incorporated by reference in their entirety.

6. Further Methods of Applying a Stabilization Device

[0497] **FIGURES 104 - 107** illustrate further methods of applying various types of motion preserving stabilization devices through an access device. The term "access device" is used in its ordinary sense (i.e. a device that can provide access) and is a broad term and it includes structures having an elongated dimension and defining a passage, e.g., a cannula or a conduit. These and similar methods also can be used to deliver any suitable stabilization device, including those hereinbefore described. Also, some aspects of these methods may be similar to or combinable with the methods described above in connection with the application of single or multi-level fixation devices.

[0498] **FIGURE 104** shows that in one method, an access device 6504 is advanced through an incision 6508 in the skin and is further advanced to a surgical location adjacent the spine of the patient. The term "surgical location" is used in its ordinary sense (i.e. a location where a surgical procedure is performed) and is a broad term and it includes locations subject to or affected by a surgery. The term "spinal location" is used in its ordinary sense (i.e. a location associated with a spine) and is a broad term and it includes locations near a spine that are sites for surgical spinal procedures. The access device 6504 may be advanced generally posteriorly. The terms "posterior" and "posteriorly" are used in their ordinary sense (i.e., from or through the rear-facing side of the patient) and are broad terms and they include an approach along any line generally behind and between the two lateral sides of the patient. In the illustrated embodiment, the access device 6504 is advanced along a generally postero-lateral approach and is positioned above a portion of the spine. In one application, the access device 6504 is positioned above at least one pedicular area of at least one of two adjacent vertebrae. In another application, the access device 6504 may be positioned above one or more pedicular areas of more than two adjacent vertebrae.

[0499] The access device 6504 may be similar to those described above, e.g., the expandable conduit 20, except as set forth below. The access device 6504 preferably has an elongate body 6510 that extends between a proximal end 6512 and a distal end 6516. The elongate body 6510 has a length between the proximal end 6512 and the distal end 6516 that is selected such that when the access device 6504 is applied to a patient during a surgical procedure, e.g., as shown in **FIGURES 104 - 107**, the distal end 6516 can be positioned inside the patient adjacent a spinal location. When so positioned, the selected length of the elongate body 6510 is such that the proximal end 6512 is located outside the patient at a suitable height.

[0500] In one embodiment, the elongate body 6510 comprises a proximal portion 6520 and a distal portion 6524. The proximal portion 6520 may have a generally oblong, oval, circular, or other suitable shape. The term "oblong" is used in its ordinary sense (i.e. having an elongated form) and is a broad term and it includes a structure having a dimension, especially one of two perpendicular dimensions, such as, for example, width or length, that is greater than another. The term "oval" is used in its ordinary sense (i.e., egg like or elliptical) and is a broad term and includes oblong shapes having curved portions and oblong shapes having parallel sides and curved portions. The access device 6504 may further have a circular cross-section near the proximal end 6512, near the distal end 6516, at the proximal and distal ends 6512, 6516, and from

the proximal end 6512 to the distal end 6516. As discussed above, in another embodiment, the access device 6504 has an oblong cross-sectional shape in the proximal portion 6520. In particular, the access device 6504 may have an oblong cross-section near the proximal end 6512, near the distal end 6516, at the proximal and distal ends 6512, 6516, and from the proximal end 6512 to the distal end 6516.

[0501] The access device 6504 preferably is capable of having a first configuration for insertion to the surgical location over the two vertebrae, which may be a relatively low-profile configuration, and a second configuration wherein increased access is provided to the surgical space. In the second configuration, the distal end 6516 may have a cross-sectional area that is larger than that of the first configuration at the distal end 6516. The distal portion 6524 of the access device 6504 may be expanded from the first configuration to the second configuration using an expander apparatus, such as the expander apparatus 200, as discussed above in connection with the skirt portion 24. When so expanded, the distal portion 6524, at the distal end 6516, defines a surgical space that includes a portion of at least one vertebra, and preferably two adjacent vertebrae.

[0502] The proximal and distal portions 6520, 6524 preferably are pivotally coupled to each other, as indicated by the arrows 6528 in **FIGURE 104**. The arrows 6528 indicate that the proximal portion 6520 may be pivoted medially and laterally with respect to the distal portion 6524. This pivotal motion tends to expose to a greater extent medial and lateral portions of the surgical space defined within the perimeter of the distal end 6516 of the access device 6504. In particular, pivoting the proximal portion 6520 laterally with respect to the distal portion 6524 exposes a portion of one or more vertebrae (or a portion of an external surface of an annulus A of an intervertebral disc) generally closer to the midline of the spine. Similarly, pivoting the proximal portion 6520 medially with respect to the distal portion 6524 exposes a portion of one or more vertebrae (or a portion of an external surface of the annulus A) generally closer to the transverse processes of the vertebrae.

[0503] In a like manner, as discussed further below, pivotal motion can be provided in the cephalad-caudal direction to expose generally cephalad or generally caudal peripheral portions of the surgical space defined within the perimeter of the distal end 6516.

[0504] At least one passage 6530 extends through the elongate body 6510 between the proximal end 6512 and the distal end 6516. The passage 6530 provides visualization of the surgical space in any suitable manner, e.g., by a viewing element, as discussed above. The passage 6530 also can provide sufficient access to the surgical space, e.g., adjacent the spine, such that components of a wide variety of dynamic stabilization systems, as well as implements adapted to deliver and apply such components, may be passed therethrough to the surgical location.

[0505] As discussed above, in the method illustrated by **FIGURE 104**, the distal end 6516 of the access device 6504 may be inserted postero-laterally, to a surgical location adjacent to at least one vertebra and preferably adjacent to the first vertebra V_1 and the second vertebra V_2 (See **FIGURE 105**).

Insertion of the access device 6504 may be facilitated by first delivering a series of dilators, as discussed above in connection with the expandable conduit 20. In one application, as discussed above, after the access device 6504 has been delivered, it can be expanded to the second configuration, as indicated schematically in **FIGURE 104**. Further details of various additional embodiments of the access device 6504 may be found in U.S. Patent Application Serial No. 10/678,744, filed October 2, 2003, entitled MINIMALLY INVASIVE ACCESS DEVICE AND METHOD, which is hereby incorporated by reference herein in its entirety.

[0506] After the access device 6504 is delivered, a stabilization device 6540 is applied to the patient. In one embodiment, the stabilization device 6540 is configured to stabilize at least two adjacent vertebrae while preserving a degree of motion. The term "dynamic stabilization" is used in its ordinary sense (i.e., stabilizing adjacent vertebrae while permitting some degree of motion) and is a broad term and it includes stabilization that allows movement on a macroscopic or a microscopic level between adjacent vertebrae. The term "motion preserving" or "motion preservation" are used in their ordinary senses (i.e., maintaining the ability for motion or movement) and is a broad term and it includes restoring at least some motion that had been lost due to spinal conditions. In one embodiment, the stabilization device 6540 includes a fastener, e.g., a bone anchor 6544, to be secured to each vertebrae V_1, V_2 and a connecting element 6548 configured to couple with the bone anchors 6544 and to extend between the adjacent vertebrae and to preserve motion of the adjacent vertebrae with respect to each other. The bone anchor 6544 may be a screw that is similar to a standard pedicle screw or may be similar to the fastener 600. In one embodiment, the bone anchor 6544 has an elongate body 6552 that extends between a proximal end 6556 and a distal end 6560. The distal end 6560 preferably is configured to engage bone, e.g., a vertebrae, in a suitable manner. In one embodiment, threads extend proximally from the distal end 6560. The proximal end 6556 of the bone anchor 6544 is configured to reside a suitable height above a vertebra when the bone anchor 6544 is applied thereto and to couple with the connecting element 6548 in a suitable manner, e.g., in a manner similar to the coupling between the elongated member 650 and the fastener 600.

[0507] The stabilization device 6540 is configured to allow movement, on a macroscopic or a microscopic level, between adjacent vertebrae to which it is applied. In one embodiment, the connecting element 6548 is configured such that motion is permitted at the point at which the connecting element 6548 is coupled with the bone anchor 6544 (See **FIGURE 96**). In another embodiment, the connecting element 6548 is configured such that movement is allowed at a location between two adjacent bone anchors 6544 applied to two adjacent vertebrae (See **FIGURE 100**).

[0508] In one application, the bone anchor 6544 is advanced through the proximal end 6512 of the access device 6504, through the passage 6530, and to the surgical location defined by the distal portion 6524 of the access device 6504. Thereafter, the bone anchor 6544 is advanced into a portion of a bone, e.g., into a pedicle of a vertebra which is to be dynamically stabilized.

[0509] Prior to insertion of the stabilization device 6540, surgical tools may be delivered through the access device 6504 to prepare the vertebrae V_1, V_2 to receive the bone anchors 6544. In various methods, bone probes, taps, or sounders may be inserted through the access device 6504 in order to perform procedures, e.g., drill and tap holes in the pedicle structures. Sounders may be used to assess the integrity of the portion of the vertebra or other bone where the bone anchor 6544 is to be applied. Bone probes may be used to make the initial invasion into the bone. Taps may be used to thread a hole or to create a threaded hole in the bone into which a bone anchor 6544 may be advanced. Any other useful instruments or preparatory procedures known to those skilled in the art may also be used in various applications. These instruments preferably have lengths chosen such that when they are inserted through the access device 6504 to the surgical space, their proximal ends extend proximally of the proximal end 6512 of the access device 6504. This arrangement permits the surgeon to manipulate these instruments proximally of the access device 6504.

[0510] The bone anchor 6544 may be advanced by any suitable implant insertion tool, e.g., a bone anchor insertion tool 6580. In one embodiment, the bone anchor insertion tool 6580 is an elongate body 6584 that extends from a proximal end (not shown) configured to be grasped, e.g., manually by the surgeon, to a distal end 6588 and defines a length therebetween. The length of the elongate body 6584 is selected such that when the bone anchor insertion tool 6580 is inserted through the access device 6504 to the surgical space, the proximal end extends proximally of the proximal end 6512 of the access device 6504. This arrangement permits the surgeon to manipulate the bone anchor insertion tool 6580 proximally of the access device 6504.

[0511] The distal end 6588 is configured to engage the proximal end 6556 of the bone anchor 6544. For example, the distal end 6588 may have a cavity 6592 shaped to receive the proximal end 6556 of the bone anchor 6544. In one embodiment, the cavity 6592 engages the proximal end 6556 of the bone anchor 6544 in a manner to enable the bone anchor 6544 to be advanced, e.g., by transferring torsion applied to the proximal end of the bone anchor tool 6580 to the bone anchor 6544, into the pedicle or other bone segment. In another embodiment, the bone anchor insertion tool 6580 has a grip portion configured to engage the bone anchor 6544. In one embodiment, both the grip portion and the bone anchor 6544 are hexagonal and are configured such that the width of the proximal end of the bone anchor 6544 is slightly less than the width of the grip portion. Other means of coupling the bone anchor insertion tool 6580 to the bone anchor 6544 that permit the bone anchor 6544 to be inserted through the access device 6504 could also be used.

[0512] As discussed above, in one embodiment, the access device 6504 provides pivotal motion between the proximal and distal portions 6520, 6524, as indicated by the arrows 6528. This pivotal motion enables the bone anchor 6544 to be applied within a range of angles with respect to the mid-plane of

the spine. This enables the surgeon to select a preferred orientation of the bone anchor 6544 with respect to the vertebrae or other bone segment.

[0513] After the desired orientation of the bone anchor 6544 has been selected and the bone anchor 6544 has been advanced into the vertebra, as indicated in **FIGURE 104**, the bone anchor insertion tool 6580 may be disengaged from the proximal end 6566 of the bone anchor 6544 and withdrawn from the access device 6504, as indicated by the arrow 6596.

[0514] **FIGURE 105** shows that in one application, the access device 6504 is configured to extend between two adjacent vertebrae V_1, V_2 and to provide access to at least a portion of a pedicle of each of the vertebrae V_1, V_2 at the same time. In this manner, a first bone anchor 6544a may be applied to the first vertebra V_1 and a second bone anchor 6544b may be applied to the second vertebra V_2 (which may be superior or inferior to the first vertebra V_1) without the need to repeat the steps of inserting the access device 6504 over each vertebra to provide access to the pedicles thereof. Two separate access devices may be used to access the pedicles of adjacent vertebrae or one access device may be inserted twice, once over each of the adjacent vertebra. Further variations and combination are also possible, e.g., one or two access device may be applied on each side of the mid-line of the spine to access three adjacent vertebrae so that a multi-level dynamic stabilization device may be applied to couple three adjacent vertebrae. These procedures may be repeated on each side of the mid-line of the spine to apply multi-level dynamic stabilization devices on each side thereof.

[0515] An arrow 6594 in **FIGURE 105** indicates that the proximal portion 6520 may be pivoted with respect to the distal portion 6524 to provide access to the peripheral regions of the surgical space defined by the distal end 6512 of the access device 6504. This arrangement may simplify or facilitate the insertion of the bone anchors 6544a, 6544b.

[0516] Once the bone anchors 6544a, 6544b are applied to the patient, the connecting element 6548 may be advanced into the proximal end 6512 of the access device 6504, through the passage 6530, to the surgical location. Once at the surgical location, the connecting element 6548 may be coupled with the bone anchors 6544a, 6544b in a suitable manner. As discussed above, one arrangement preserves motion of the vertebrae V_1, V_2 by permitting movement at or near the coupling of one or both of the connecting element 6548 and the bone anchors 6544. Another arrangement preserves motion of the vertebrae V_1, V_2 by permitting movement at a location between the bone anchors 6544a, 6544b. Another arrangement preserves motion of the vertebrae V_1, V_2 by permitting movement both at or near the connecting element / bone anchor coupling(s) and at a location between the bone anchors 6544a, 6544b.

[0517] In one embodiment, the connecting element 6548 is a flexible member that permits a degree of motion between the vertebrae V_1, V_2. **FIGURE 106** shows another embodiment of a connecting element 6598 that is a dynamic connecting element, e.g., an element that is configured such that movement is allowed at a location along the connecting element 6598 at a location between two adjacent bone anchors

6544 applied to two adjacent vertebrae (See **FIGURE 100**). In one embodiment, the connecting element 6598 has a first member 6600 coupled with the first bone anchor 6544a, and thereby with the first vertebra V_1, and a second member 6604 coupled with the second bone anchor 6544b, and thereby coupled with the second vertebra V_2. The first and second members 6600, 6604 may be rigid members or they may be flexible. The first member 6600 has a first end 6608 configured to couple with the first bone anchor 6544a and a second end with a chamber 6612 formed therein. The second member 6604 has a first end 6616 configured to couple with the second bone anchor 6544b and a second end with a piston 6620 arranged thereon. When the connecting element 6598 is assembled, the piston 6620 is arranged to move within the chamber 6612, providing motion indicated by an arrow 6624. The coupling of the piston 6620 and the chamber 6612 could also permit rotational motion of the first and second members 6600, 6604 as indicated by arrows 6628. The piston and chamber arrangement could be configured to permit a degree of pivoting of the first member 6600 with respect to the second member 6604, as indicated by an arrow 6632. Other arrangements of connecting elements could employ spring mechanisms, ball-and-socket joints, or any of the other geometries or arrangements described hereinabove.

[0518] The access device 6504 is advantageously configured to permit the foregoing steps to be performed in any order. For example, the connecting elements 6548, 6598 may be advanced to the surgical location before or after the first bone anchor 6544a is applied to the first vertebra V_1. In a like manner, the connecting elements 6548, 6598 may be advanced to the surgical location before the second bone anchor 6544b is applied to the second vertebra V_2. The connecting element 6548, 6598 may further be coupled with the first bone anchor 6544a before the second bone anchor 6544b is applied to the second vertebra V_2. Other orders of the foregoing steps are also possible.

[0519] In one procedure, once the bone anchors 6544 have been attached to the two adjacent vertebrae V_1, V_2, the connecting element 6548, 6598 may be delivered through the access device 6504 to couple with the bone anchors 6544. To facilitate insertion, a gripping apparatus, such as, e.g., the guide apparatus 800 described above, may be used to engage the connecting element 6548, 6598 and manipulate it through the access device 6504 to the surgical space. The connecting elements 6548, 6598 may take many forms depending on the particular stabilization device being delivered and the combination of vertebrae being treated.

[0520] In one embodiment, shown in **FIGURE 105**, the connecting element 6548 is a flexible member, such as that described above for stabilization device 6200. In another embodiment, shown in **FIGURE 106**, the connecting element 6598 may comprise a jointed link rod, such as that described above for stabilization device 6250.

[0521] Once the connecting element 6548, 6598 is appropriately seated on or near the bone anchors 6544, clamping elements may be inserted through the access device 6504 in a manner similar to that described above. The clamping elements may then be threadably or otherwise engaged with the bone

anchors 6544, fixing the connecting element 6548, 6598 between the clamping element and the bone anchors 6544.

[0522] In some applications, a second access device, such as an expandable conduit 20 or other suitable access device, may be inserted into the patient. For example, a second access device could be inserted through a postero-lateral approach on the contralateral side of the spine, e.g., the opposite side of the spine across the mid-line of the spine, as indicated by an arrow 6636, to provide access to at least one of two or more adjacent vertebrae. In another embodiment, a second access device may be inserted through an alternative approach on the same or opposite side of the spine to provide access to at least one of two or more adjacent vertebrae. This second access device may provide access to the vertebrae at about the same time as the first access device 6504 or during a later or earlier portion of a procedure. In one method, two stabilization devices are inserted from both sides of the spine using first and second access devices. Any combination of single, multiple stabilization devices, or stabilization device sub-components may be delivered through one or more access devices from any combination of one or more approaches, such as the approaches shown in **FIGURES 104-107**, or any other suitable approach.

[0523] **FIGURE 107** shows schematically another form of a dynamic stabilization treatment that could be provided through the access device 6504. In this treatment, one or more facet joints are removed and one or more artificial facet joints are inserted in their place. As above, the access device 6504 is delivered to the surgical location and is configured to provide access to a surgical location.

[0524] The facet joint may be removed using any suitable technique. Preferably, the facet joint is removed by inserting one or more implements to the surgical location through the access device 6504 and withdrawing facet joint fragments from the surgical location through the access device 6504.

[0525] After the facet joint is removed, a facet joint insertion tool 6660 may be advanced into the access device 6504 and may be advanced through the passage 6530 to a location adjacent where the natural facet joint had been.

[0526] The facet joint insertion tool 6660 preferably has an elongate body with a proximal end (not shown) that is configured to be manipulated by a surgeon and a distal end 6664 that is configured to selectively engage an artificial facet joint configured to preserve motion of the vertebrae forming the face joint. One such artificial face joint is the replacement facet joint 6668. Preferably the distal end 6664 includes a releasable clamp 6672 or other means for engaging the facet joint. In one embodiment, the clamp 6672 is releasable at the proximal end of the facet joint insertion tool.

[0527] The replacement facet joint 6668 preferably includes a generally superior member 6676, a generally inferior member 6680, and a connecting member 6684 that is positioned between the superior member 6676 and the inferior member 6680. The superior member 6676 is configured to engage the generally superior aspect of the facet portion of the vertebra V_1. The inferior member 6680 is configured to engage the generally inferior aspect of the facet portion of the vertebra V_2. In one embodiment, bone

growth features are provided on the surfaces of the superior and inferior members 6676, 6680 that are intended to engage the vertebral surfaces facing the facet joint. Although the bone growth features are shown as spikes in the illustrated embodiment, they may take any other suitable form. The connecting member 6684 is a deformable member in one embodiment that permits movement of the facets of the vertebrae V_1, V_2 with respect to each other to provide dynamic stabilization of the vertebrae V_1, V_2.

[0528] **FIGURE 107** illustrates at least two stages of a method for implanting replacement facet joint by way of the access device 6504 to provide dynamic stabilization. In one stage, when the replacement facet joint 6668 has been advanced to the surgical location, the facet joint insertion tool 6660 is caused to release the replacement facet joint 6668. This stage is represented by the schematic depiction of the replacement facet joint 6668 located between the distal end of the facet joint insertion tool 6660 and the vertebrae V_1, V_2. In another stage, the replacement facet joint 6668 is coupled with the adjacent vertebrae V_1, V_2 to form a replacement joint, as shown by the dashed outline of a replacement facet joint in positioned where the natural facet joint had been.

[0529] The proximal portion 6520 of the access device 6504 is pivotal with respect to the distal portion 6524 thereof, as illustrated by the dashed line representation of the proximal portion 6520 and the arrow 6594, as discussed above. This may facilitate one or more of the foregoing steps of facet joint replacement dynamic stabilization.

[0530] Although the forgoing procedures are described in connection with a single level postero-lateral procedure, other procedures are possible. For example, multiple level stabilization could be performed with the expandable conduit 20 or other suitable access device as described above with reference to **FIGURES 30-37**. As discussed above, other applications are also possible in which the access device 6504 is not expanded prior to delivery of the stabilization device 6500. In such applications, the access device 6504 remains in the first configuration while some, all, or any of the steps described above are performed. Also, a motion preserving stabilization procedure could be combined with various spinal procedures used to partially fuse or rigidly fix adjacent vertebrae for stabilization along any suitable approach, e.g., anterior, lateral, posterior, transforaminal.

[0531] Although the methods discussed above are particularly directed to the insertion of a stabilization device, the access device 6504 may also be used advantageously to extract or remove the stabilization device. The surgical tools also may be further configured to facilitate removal as well as insertion. In one application, a motion preserving stabilization device may be replaced with a generally inflexible stabilization device, such as those described above, through the access device 6504. In another application, a previously inserted generally inflexible stabilization device may be replaced with a motion preserving stabilization device, such as those described above, through the access device 6504.

[0532] The foregoing methods and apparatuses advantageously provide minimally invasive treatment of a person's spine in a manner that preserves some degree of motion between the vertebrae.

Accordingly, trauma to the patient may be reduced thereby, and recovery time shortened. As discussed above, the stabilization devices described herein provide a more normal post-recovery range of motion of the spine, which can reduce the need for additional procedures.

D. Apparatuses, Systems and Methods for Stabilizing the Spine Using Transfacet Fasteners

[0533] As discussed above, the systems disclosed herein provide access to a surgical location at or near the spine of a patient to enable procedures to be performed on the spine. These procedures include translaminar facet screw fixation and transfacet pedicle screw fixation to stabilize two adjacent vertebrae. Both of the above mentioned procedures are generally transfacet fixation procedures. Translaminar includes penetration by the fastener through portions of both the spinous process, the lamina, and the facet joint. They can be used alone or in conjunction with the fixation techniques discussed herein, including but not limited to: bone graft materials, or fixation devices placed in the actual disc space to promote fusion of the vertebrae.

[0534] In one embodiment, an access device is inserted into the patient to provide access to a spinal location, as described above. A variety of anatomical approaches may be used to provide access to a spinal location using the expandable conduit. The access device preferably is inserted generally posteriorly. As used herein the phrase "generally posteriorly" is used in its ordinary sense and is a broad term that refers to a variety of surgical approaches to the spine that may be provided from the posterior side, i.e., the back, of the patient, and includes, but is not limited to, posterior, postero-lateral, and transforaminal approaches. Any of the access devices described or incorporated herein, such as the expandable conduit, could be used. Referring to the proximal and distal ends of these access devices, they may be circular, oblong, oval or another shape. The shape of one end need not determine the shape of the other. The term "oblong" is used in its ordinary sense (i.e. having an elongated form) and is a broad term, and it includes a structure having a dimension, especially one of two perpendicular dimensions, such as, for example, width or length, that is greater than another. The term "oval" is used in its ordinary sense (i.e., egg like or elliptical) and is a broad term and includes oblong shapes having curved protions and oblong shapes having parallel sides and curved portions.

[0535] Further details of various additional embodiments of the access device may be found in U.S. Patent Application Serial No. 10/678,744, filed October 2, 2003, entitled MINIMALLY INVASIVE ACCESS DEVICE AND METHOD, and in U.S. Provisional Patent Application No. 60/513,796, filed October 22, 2003, both of which are hereby incorporated by reference herein in their entirety.

[0536] The distal end of the access device may be placed at the desired surgical location, e.g., adjacent the spine of the patient, with a central region of the access device over a first vertebrae. In one procedure, the distal end of the access device is inserted until it contacts at least a portion of at least one of the vertebrae being treated or at least a portion of the spine. In another procedure, the distal end of the access device is inserted until it contacts a portion of the spine and then is withdrawn a small amount to provide a selected gap between the spine and the access device. In other procedures, the access device

may be inserted a selected amount, but not far enough to contact the vertebrae being treated, the portion of the vertebrae being treated, or the spine.

[0537] The access device may be configured, as described above, to provide increased access to the surgical location. The access device can have a first configuration for insertion to the surgical location over the first vertebra and a second configuration wherein increased access is provided to the target vertebrae. The first configuration may provide a first cross-sectional area at a distal portion thereof. The second configuration may provide a second cross-sectional area at the distal portion thereof. The second cross-sectional area preferably is enlarged compared to the first cross-sectional area. In some embodiments, the access device may be expanded from the first configuration to the second configuration to provide access to the adjacent vertebrae either above the first vertebra, below the first vertebra, or both.

1. Transfacet Spinal Stabilization using Translaminar Fact Screw Fixation

[0538] In one embodiment of this invention, translaminar facet screw fixation is achieved using one or more access devices to achieve access to the spine. Translaminar facet screw fixation includes a stabilization fastener through portions of the spinous process, the lamina and the facet joint. There are multiple ways of achieving access using the access devices. In one embodiment, access is gained using two devices, one access device on the ipsalateral side and one on the contralateral side of the spine. It is useful to define several axes in **FIGURE 108** to describe the placement of the access device relative to the spine. A spinal axis S runs generally along the spine of the patient from head to toe, or top to bottom of the figure. A transverse axis T runs generally laterally across the spine from right to left in the figure. A posterior axis P runs generally in line with the spinous process out from the page. In this embodiment, each access device preferably enters from a generally posterior approach and rests at or near the desired spinous process, preferably at a first angle A1 of approximately 0 to 90 from the plane defined by the spinal axis S and the posterior axis P (hereinafter "S-P plane"), a second angle A2 of approximately 0 to 60 from the plane defined by the transverse axis T and the posterior axis P (hereinafter "T-P plane"), and a third angle A3 (not shown) of approximately 0 to 90 from the plane defined by the spinal axis S and the transverse axis T (hereinafter "S-T plane"). More preferably, the first angle A1 is approximately 25 to 65 from S-P plane, the second angle A2 is 15 to 45 from the T-P plane, and the third angle A3 is 25 to 65 from the S-T plane. These angles are largely determined by the structure of the individual spine that the doctor addresses in each operation and should not be considered strict requirements for this embodiment.

[0539] **FIGURE 108** shows one placement of the access device 20 to allow insertion of the fasteners and other tools used for the procedure. In this embodiment, an access device 20 is envisioned with a diameter of 16-24 mm with an actuatable section expandable to between 25 and 40 mm. This and other embodiments may use an access device 20 of greater or smaller diameter. Once the access device 20 is inserted, its distal end may be actuated from a first configuration to a second configuration to allow sufficient space for the physician to manipulate the tools and equipment to effect a proper stabilization. A similar procedure is used to gain access to the spine through the access device 20 on the other side of the spine. In

all cases, the access device 20 may be used either with or without an endoscope, allowing visualization of the surgical location through direct view or an enhanced means depending upon the physician's preference.

[0540] In another embodiment, the access device 20 can be expanded to provide access to more than one spinous process 7010, opening the door to multilevel fixations. The approach would be similar to the above-described approach; however, the actuated portion of the access device would be expanded to reveal multiple vertebrae.

[0541] With the access device 20 oriented as described above, the doctor can then stabilize the vertebrae using translaminar facet screw fixation. **FIGURES 109 and 110** illustrate how the vertebrae are stabilized using translaminar facet screw fixation. Two fasteners 7020a and 7020b are used to secure the vertebrae. In a preferred embodiment, the physician will initiate the procedure by accessing the spine through the access device 20 and scoring the bone at or near the base of the spinous process 7010 with a drill, wire, probe, or some other similar device known in the art, to offer a starting point to create a translaminar tunnel 7060. The bone through which the fasteners are to run may be optionally tapped, pre-drilled or marked in some other manner to allow for ease and accuracy when inserting the fasteners 7020a and 7020b.

[0542] In a preferred embodiment, a translaminar tunnel 7060 is created with a drill D1 as depicted in **FIGURE 111**, the diameter of said tunnel 7060 being small enough to allow sufficient purchase for the fasteners to actively engage the bone material while being large enough to allow for an accurate insertion of the fastener. The tunnel 7060 travels through a portion of the spinous process 7010 and into a portion of the facet joint 7030a. It may also pass through a portion of the lamina 7090a at the base of the spinous process 7010. Further, the drill D1 may be advanced through an access device (not shown) as described above. The translaminar tunnel 7060 may be created using a wire, probe, drill, or other similar device known in the art. In a preferred embodiment, the fastener 7020a used in this procedure provide the stabilization required to allow the bone of the adjacent vertebrae to fuse. The actuated access device 20 provides additional space to the operating physician while minimizing trauma to the surrounding tissue. **FIGURE 112** shows the entry hole 7080 of a translaminar tunnel after the drill D1 has been removed.

[0543] With the translaminar tunnel 7060 in place, the physician can, through an access device, introduce a first fastener 7020a to the desired vertebrae. This fastener 7020a is secured through the spinous process 7010 of the first vertebrae V1, through the facet joint 7030b on the contralateral side from the insertion point 7040a and into the base 7050b of the pedicle of the second vertebrae V2 using a screw driver or similar mechanical device D2 for assisted insertion passing through the access device 20 and coming into mechanical contact with the fastener 7020a. In other embodiments, the fastener 7020a may reach the apex of the pedicle or may not enter the pedicle at all, rather travelling though the lateral facet near the transverse process 7070b.

[0544] Access is gained though a second access device 20 as described above and a second fastener 7020b may be similarly inserted through the access device 20 and secured to the vertebrae through

the spinous process 7010 and a portion of the lamina 7090a of the first vertebrae V1, this time at insertion point 7040b, traveling through the facet joint 7030a on the side opposite the insertion point 7040b and into the base 7050a of the pedicle of the second vertebrae V2. In alternative embodiments, the fastener 7020b used to secure the vertebrae may reach other portions of the pedicle other than the base, and/or may not reach the pedicle at all. Alternative embodiments may have the fastener travel through the lateral facet near the transverse process or any combination of this with the above-discussed portions of the vertebrae. These fasteners 7020a and 7020b may comprise screws, straight pins or tapered pins pressed into or bonded to the bone such that they travel through the two vertebrae securing them together. In addition, said fasteners 7020a and 7020b may be composed of a number of biocompatible, stiff materials, including metal material, polymeric material, ceramic material, or other synthetic or naturally stiff material with similar characteristics. In a preferred embodiment, the fasteners 7020a and 7020b are screws made of a metallic material. **FIGURE 113** shows a fastener 7020a being inserted into the vertebra V1. **FIGURE 114** shows both fasteners 7020a and 7020b fully inserted, securing the vertebrae V1 and V2. Translaminar facet screw fixation is further described in an article by F. Magerl entitled "Stabilization of the lower thoracic and lumbar spine with external skeletal fixation." *Clin Orthop* 1984; 189; 125-41, the entirety of which is hereby incorporated by reference.

2. Spinal Stabilization using Transfacet Pedicle Screw Fixation

[0545] In one embodiment of this invention, transfacet pedicle screw fixation is achieved using one or more access devices to achieve access to the spine. Transfacet pedicle screw fixation includes the penetration of a fastener through at least a portion of the facet joint. There are multiple ways of achieving access using the access devices. In one embodiment, access is gained using one access device to insert all tools and fasteners needed in the procedure. In this embodiment, an access device is envisioned with a diameter of 16-24 mm with an actuatable section expandable to between 25 and 40 mm. This and other embodiments may use an access device of greater or smaller diameter. In this embodiment, the access device preferably enters from a generally posterior approach and rests at or near the desired vertebrae. Once the access device is inserted, its distal end may be actuated from a first configuration to a second configuration to allow sufficient space for the physician to manipulate the tools and equipment to effect a proper stabilization. **FIGURE 115** shows the access device 20 in one possible position at the spine with the distal end actuated to allow more freedom in the surgical space. It would rest at or near the spine at a generally posterior angle to accommodate the angle of insertion necessary to place the fasteners. The spinous process 7010 may be within the working space defined by the access device 20 or adjacent the space. Using the planes of the spine as defined above, the access device 20 in this embodiment would preferably lie at a first angle A1 of approximately 0 to 45 from the S-P plane, a second angle A2 of approximately 0 to 60 from the T-P plane, and a third angle A3 of approximately 45 to 100 from the S-T plane. More preferably, the first angle A1 is approximately 0 to 10 from S-P plane, the second angle A2 is 10 to 45 from the T-P plane, and the third angle A3 is 45 to 80 from the S-T plane. These angles are largely determined by the structure of the individual spine that the doctor addresses in each operation and

should not be considered strict requirements for this embodiment. In another embodiment, the access device herein discussed may be expanded to cover multiple vertebrae, allowing application of the transfacet pedicle screw fixation to multiple levels from a single access device. Thus, it is possible to perform this fixation technique using one or more access devices. In all cases, the access device may be used either with or without an endoscope.

[0546] Another possible embodiment would place a single access device over multiple vertebrae. The access angle would be similar to the above-described, with the actuated portion of the access device open sufficiently to span two or more spinous processes, thus allowing the physician to fix three vertebra with 2 or more fasteners.

[0547] In another embodiment, a separate access device is used on either side of the spinous process to effect the transfacet pedicle screw fixation. In such an embodiment, the access device can be actuated to cover one or more vertebrae per side, allowing for single or multilevel fixation. The approach angle would be similar to that described above with the access device shifted laterally to address specific sides of the vertebrae.

[0548] With the access device oriented as described above, the doctor can then stabilize the vertebrae using transfacet pedicle screw fixation. **FIGURES 115 - 117** illustrate how the vertebrae are stabilized using transfacet pedicle screw fixation. Two fasteners 7020a and 7020b are used to secure the vertebrae. In a preferred embodiment, the physician will initiate the procedure by accessing the spine through the access device 20 and scoring the bone on the facet joint with a drill, wire, probe, or some other similar device known in the art to offer a starting point for insertion of the fasteners. In one embodiment, the bone through which the fasteners are to run may be optionally tapped, pre-drilled or marked in some other manner to allow for ease and accuracy when inserting the fasteners. In a preferred embodiment, the bone is scored at the entry point to the facet joint and the fasteners 7020a and 7020b are inserted without a pre-drilled hole.

[0549] Once a starting point has been marked, the physician can, though an access device 20, introduce a first fastener 7020a to the desired vertebrae. This fastener 7020a is secured through the facet joint 7030a into the base 7050a of the pedicle of the second vertebrae V2 using a screw driver or similar device D2 passing through the access device 20 and coming into mechanical contact with the fastener 7020a. Because of the second, expanded configuration at the distal end of the access device 20, a second fastener 7020b is similarly secured through the same access device 20 on the side opposite the first fastener 7020a, travelling through the facet joint 7030b into the base 7050b of the pedicle of the second vertebrae V2. The angle of the access device 20 may be altered laterally as needed to facilitate insertion of the fasteners. These fasteners 7020a and 7020b may comprise screws, straight pins or tapered pins pressed into or bonded to the bone such that they travel through the two vertebrae securing them together. In addition, said fasteners 7020a and 7020b may be composed of a number of biocompatible, stiff materials, including metal material, polymeric material, ceramic material, or other synthetic or naturally stiff material with similar characteristics.

In a preferred embodiment, the fasteners 7020a and 7020b are screws made of a metallic material. Transfacet pedicle screw fixation is further described in an article by H. Boucher entitled "Method of spinal fusion." *Clin Orthop* 1997; 335; 4-9, the entirety of which is hereby incorporated by reference.

[0550] In another embodiment, two access devices are used to accomplish the transfacet pedicle screw fixation. **FIGURE 116** shows an example of how the access devices 20 might be placed to accomplish such a fixation. The exact angle is determined by the spinal structure and the angle required to insert the fasteners 7020a and 7020b into the bone. In this embodiment, each access device 20 may enter from a generally posterior approach and rests at or near the desired facet joint, preferably at a first angle A1 of approximately 0 to 60 from the S-P plane, a second angle A2 of approximately 0 to 60 from the T-P plane, and a third angle A3 (not shown) of approximately 0 to 90 from the S-T plane. More preferably, the first angle A1 is approximately 15 to 45 from S-P plane, the second angle A2 is 15 to 45 from the T-P plane, and the third angle A3 is 40 to 80 from the S-T plane. These angles are largely determined by the structure of the individual spine that the doctor addresses in each operation and should not be considered strict requirements for this embodiment.

[0551] As described above, the bone through which the fasteners are to run may be optionally tapped, pre-drilled or marked in some other manner to allow for ease and accuracy when inserting the fasteners. In a preferred embodiment, the fasteners provide the stabilization required to allow the bone of the adjacent vertebrae to fuse. In one embodiment of this stabilization technique, a single insertion point through the back and a single access device are used to conduct the entire operation to further minimize the trauma to surrounding tissue in the region of the desired stabilization. Though a narrow cannula may provide access for insertion of a single fastener, the access device described herein allows the necessary room to insert several fasteners at angles to each other. It should be noted that though a single access device may be used, multiple access devices may be used to facilitate the operation.

[0552] It is to be understood that the fixation techniques herein described may be used in combination with any number of other spinal operations, including but not limited to discectomy, nucleotomy, laminectomy, laminotomy, distraction, posterior-lateral fusion, etc..

[0553] Further details of the expandable conduit and its applications are described in U.S. Patent Application No. 10/658,736, filed September 9, 2003, which is herein incorporated by reference in its entirety.

III. FURTHER SURGICAL INSTRUMENTS TO FACILITATE THE PROCEDURES DESCRIBED ABOVE

[0554] The above systems and methods for performing spinal procedures may be facilitated by use of specialized surgical instruments. In one preferred embodiment, a steerable endoscopic surgical instrument may be used for the cutting and/or removal of tissue, especially tissue within an interbody space. **FIGURE 118** illustrates such a surgical instrument 8010. The surgical instrument 8010 includes a handle 8012 and an actuator mechanism 8014 connected with the handle. A stem section 8016 is connected with

and projects from the handle 8012. The stem section 8016 includes a first stem section or rigid stem section 8018 and second stem section or flexible stem section 8020. The actuator mechanism 8014 bends the flexible stem section 8020 as described below.

[0555] A proximal end portion 8022 of the rigid stem section 8018 is fixed to the handle 8012. A proximal end portion 8024 of the flexible stem section 8020 is rigidly connected with a distal end portion 8026 of the rigid stem section 8018 by a soldered lap joint connection 8028. The flexible stem section 8020 may be rigidly connected to the rigid stem section 8018 in any suitable manner. A rotary cutter assembly or shaver assembly 8030 is pivotally connected with a distal end portion 8032 of the flexible stem section 8020 by a pivot connection 8034. The shaver assembly 8030 may be pivotally connected to the flexible stem section 8020 in any suitable manner.

[0556] The shaver assembly 8030 includes a fixed outer member 8036 and a rotatable inner member 8038. The outer member 8036 (**FIGURE 119**) of the shaver assembly 8030 has a generally cylindrical, tubular configuration with a first cutting edge 8040. The inner member 8038 of the shaver assembly 8030 has a generally cylindrical configuration and is rotatable within the outer member 8036 of the shaver assembly. The inner member 8038 of the shaver assembly 8030 has a second cutting edge 8042. Although a shaver assembly 8030 is shown connected with the distal end 8032 of the flexible stem section 8020, it is contemplated that any member for acting on tissue of a patient could be connected with the distal end of the flexible stem section.

[0557] A suction pump (not shown) is connected with the handle 8012 (**FIGURE 118**) at a connection indicated at 8044. A source of water or other irrigation fluid (not shown) is connected with the handle 8012 at a connection 8046. A control apparatus 8048 is connected with the surgical instrument 8010 through a cord system 8050.

[0558] The rigid stem section 8018 (**FIGURE 119**) is substantially non-bendable during use of the surgical instrument 8010. The rigid stem section 8018 has a tubular cylindrical configuration including parallel inner and outer surfaces 8052 and 8054. The inner surface 8052 defines a cylindrical central passage 8056. The rigid stem section 8018 has a longitudinal central axis 8058 which forms a longitudinal central axis of the surgical instrument 8010.

[0559] The flexible stem section 8020 (**FIGURE 119**) of the surgical instrument 8010 includes an outer tubular member 8060 for supporting the non-rotating outer member 8036 of the shaver assembly 8030 on the rigid stem section 8018 of the surgical instrument. It is contemplated that the tubular member is made of Nitinol and is superelastic at approximately 60-65 ksi. The tubular member 8060 has cylindrical radially inner and outer surfaces 8062 and 8064 that extend parallel to each other. The inner surface 8062 defines a cylindrical central passage 8068 which is a continuation of the passage 8056 in the rigid stem section 8018. The passages 8056 and 8068 provide a path for irrigation fluid. The tubular member 8060 has a longitudinal axis 8070 that is a continuation of the axis 8058.

[0560] A first plurality of wedge-shaped slots 8080 extend through the inner and outer cylindrical surfaces 8062 and 8064 and transverse to the longitudinal axis 8070. The wedge-shaped slots 8080 extend from a lower side, as viewed in **FIGURE 119**, of the longitudinal axis 8070 of the flexible stem section 8020 toward the longitudinal axis. A second plurality of wedge-shaped slots 8090 extend through the inner and outer cylindrical surfaces 8062 and 8064 and transverse to the longitudinal axis 8070. The wedge-shaped slots 8090 extend from an upper side, as viewed in **FIGURE 119**, of the longitudinal axis 8070 toward the longitudinal axis. There are nine wedge-shaped slots 8080 and eight wedge-shaped slots 8090 shown in **FIGURE 119**. It is contemplated that any number of wedge-shaped slots 8080 and 8090 may be formed in the flexible stem section 8020 depending on the length of the flexible stem section.

[0561] Each of the wedge-shaped slots 8090 is axially located between the wedge-shaped slots 8080. The wedge-shaped slots 8080 and 8090 are defined by ring portions 8092 and 8094 extending at an angle to each other and transverse to the longitudinal axis 8070. Each of the ring portions 8094 is axially located between the ring portions 8092. The ring portions 8092 and 8094 extend at an angle of approximately 10.degree. to each other. The ring portions 8092 extend generally parallel to each other and the ring portions 8094 extend generally parallel to each other.

[0562] The ring portions 8092 and 8094 are interconnected to define apexes 8100 of the slots 8080 located on the upper side, as viewed in **FIGURE 119**, of the longitudinal axis 8070. The ring portions 8092 and 8094 diverge away from each other toward the outer surface 8064 located on the lower side of the axis 8070. Accordingly, the wedge-shaped slots 8080 extend radially from the cylindrical outer surface 8064 on the lower side of the longitudinal axis 8070 to an opposite or upper side of the longitudinal axis. The ring portions 8092 and 8094 are also interconnected to define apexes 8102 of the slots 8090 located on the lower side of the longitudinal axis 8070. The ring portions 8092 and 8094 diverge away from each other toward the cylindrical outer surface 8064 located on the upper side of the axis 8070. Accordingly, the wedge-shaped slots 8090 extend radially from the cylindrical outer surface 8064 on an upper side of the longitudinal axis to a lower side of the longitudinal axis. Furthermore, each wedge-shaped slot 8080 is defined by first and second ring portions 8092 and 8094 extending at an angle to each other. The wedge-shaped slot 8090 located axially adjacent to the slot 8080 is defined by the second ring portion 8094 and a third ring portion 8092 extending from the second ring portion 8094.

[0563] The slot 8080 located adjacent the distal end 8032 of the stem section 8020 is defined by the end 8032 and ring portion 8092 extending from the end 8032. The end 8032 has a surface 8096 extending at an angle of approximately 10.degree. to the ring portion 8092 extending from the end 8032. The slot 8080 located adjacent the proximal end 8024 of the stem section 8020 is defined by the end 8024 and ring portion 8094 extending from the end 8024. The end 8024 has a surface 8098 extending at an angle of approximately 10.degree. to the ring portion 8094 extending from the end 8024.

[0564] A pair of cylindrical deflection control wire passages 8110 and 8112 (**FIGURE 120**) are formed in the inner surface 8062 of the tubular member 8060. The passages 8110 and 8112 extend parallel to each other and to the axis 8070. The passages 8110 and 8112 extend along the length of the flexible stem section 8020 and on the upper side of the longitudinal axis 8070, as viewed in **FIGURE 120**.

[0565] The actuator assembly 8014 (**FIGURE 118**) of the surgical instrument 8010 includes a deflection control lever 8130 which projects from the handle 8012. The deflection control lever 8130 is supported for pivotal movement relative to the handle 8012. The actuator assembly 8014 includes at least two elongate flexible members or deflection control wires 8132 and 8134 (**FIGURE 120**). The wires 8132 and 8134 are separate portions of a single loop of wire 8136 which has its proximal ends connected for movement with the deflection control lever 8130. The deflection control wires 8132 and 8134 are made from a superelastic metal alloy which limits stress on the actuator assembly 8014.

[0566] The deflection control wires 8132 and 8134 extend from the deflection control lever 8130 through the deflection control wire passages 8110 and 8112, respectively, in the tubular member 8060. The deflection control wires 8132 and 8134 are connected in a known manner in a force-transmitting relationship with the fixed portion 8036 of the shaver assembly 8030. It is contemplated that the control wires 8132 and 8134 loop around a fixed portion of the shaver assembly 8030. As a result, tensile forces on the control wires 8132 and 8134, resulting from movement of the actuator control lever 8130, are transmitted to the shaver assembly 8030 to bend the flexible stem section 8020.

[0567] A rotatable drive shaft 8150 (**FIGURES 119** and **120**) is disposed radially inward of the tubular member 8060 of the surgical instrument 8010. A rigid portion 8152 (**FIGURE 119**) of the drive shaft 8150 is disposed within the rigid stem section 8018. The rigid portion 8152 of the drive shaft 8150 is a cylindrical metal tube which has parallel cylindrical inner and outer surfaces 8154 and 8156. The inner surface 8154 of the rigid portion 8152 of the drive shaft 8150 defines a central passage 8158. The rigid portion 8152 of the drive shaft 8150 is connected with the drive shaft (not shown) of a suitable electric motor in the handle 8012 and is rotatable about the longitudinal central axis 8058 by operation of the motor.

[0568] A flexible tubular portion 8162 of the drive shaft 8150 is disposed within the flexible stem section 8020. It is contemplated that the flexible portion 8162 of the drive shaft 8150 could be formed of a helical coil spring or a flexible tubular polymer. The flexible portion 8162 of the drive shaft 8150 is capable of transmitting rotational force from the rigid portion 8152 of the drive shaft 8150 to the rotatable inner part 8038 of the shaver assembly 8030. The flexible portion 8162 of the drive shaft 8150 has an axially extending central passage 8164. The passages 8158 and 8164 in the drive shaft 8150 provide a suction path for tissue and fluid evacuation.

[0569] When the actuation control lever 8130 is pivoted relative to the handle 8012, so as to tension the deflection control wires 8132 and 8134, tension in the wires is effective to bend the flexible stem section 8020. The flexible stem section 8020 bends in an upward direction, as viewed in **FIGURES 118** and

119, extending parallel to the direction in which the slots 8090 extend through the inner and outer surfaces 8062 and 8064 and transverse to the axis 8070. The flexible stem section 8020 is prevented from bending in any direction extending transverse to the upward direction. The shaver assembly 8030 is pulled from an unactuated linear position, shown in **FIGURES 118** and **119**. The actuator assembly 8014 can thus be operated to change the orientation of the shaver assembly 8030 relative to the rigid stem section 8018 and relative to body tissue during an operation. The actuator assembly 8014 can be operated to positively change the orientation of the shaver assembly 8030 from the straight initial orientation. The drive shaft 8150 and the inner shaver part 8038 are rotatable to effect tissue removal while the flexible stem section 8020 is in any orientation. The superelasticity of the tubular member 8060 and the flexible portion 8162 of the drive shaft 8150 return the flexible stem section to the unactuated linear position.

[0570] Further details relating to the above described and similarly flexible instruments may be found in U.S. Patent No. 5,454,827, filed on May 24, 1994 and issued on October 3, 1995; U.S. Patent No. 5,618,294, filed on July 21, 1995 and issued on April 8, 1997; U.S. Patent No. 5,885,288, filed on June 11, 1997 and issued on March 23, 1999; U.S. Patent No. 5,851,212, filed on June 11, 1997 and issued on December 22, 1998; U.S. Patent No. 5,899,914, filed on June 11, 1997 and issued on May 4, 1999; U.S. Patent No. 5,938,678, filed on June 11, 1997 and issued on August 17, 1999; U.S. Patent No. 6,048,339, filed on June 29, 1998 and issued on April 11, 2000; U.S. Patent No. 6,053,907, filed on August 13, 1998 and issued on April 25, 2000; U.S. Patent No. 6,062,951, filed on September 24, 1998 and issued on May 16, 2000; U.S. Patent No. 6,077,287, filed on May 28, 1999 and issued on June 20, 2000; U.S. Patent No. 6,139,214, filed on December 14, 1998 and issued on October 31, 2000; and U.S. Patent No. 6,645,218, filed on August 5, 2002 and issued on November 11, 2003; which patents are hereby incorporated herein by reference in their entirety.

[0571] It will be understood that the foregoing is only illustrative of the principles of the invention, and that various modifications, alterations, and combinations can be made by those skilled in the art without departing from the scope and spirit of the invention.

WHAT IS CLAIMED IS:

1. A surgical access device comprising a passage and a distal portion, the access device being actuatable between a first configuration wherein the passage has a first cross-sectional area at the distal portion suitable for insertion into the patient and a second configuration wherein the passage has an enlarged cross-sectional area at said distal portion, the access device being capable of providing access to an interbody space, the passage capable of having a prosthetic spinal disc implant inserted therethrough to the interbody space.

2. A system for performing a minimally invasive spinal disc replacement on a patient, comprising:

the access device of Claim 1; and

an instrument capable of advancing the prosthetic spinal disc implant through the passage.

3. The system of Claim 2, wherein the instrument is capable of advancing the prosthetic spinal disc implant into the interbody space or into a space defined between a superior articular process and an inferior articular process.

4. The system of either of Claims 2 and 3 further comprising an instrument capable of removing at least a portion of a spinal disc.

5. A system for performing a multi-level procedure on a patient, comprising:

the access device of Claim 1; and

a prosthetic spinal disc implant capable of being delivered through the access device to the interbody space or to a location adjacent to an articular process.

6. The system of Claim 5, wherein the prosthetic spinal disc implant is capable of being advanced into the interbody space or into a space defined between a superior articular process and an inferior articular process.

7. A system or access device according to any of the preceding claims, wherein the access device is capable of being inserted in order to provide access along an approach selected from the group consisting of a lateral approach, a posterior approach, a postero-lateral approach, a retro-peritoneal approach, an anterior approach and a transforaminal approach.

8. A system or access device according to any of the preceding claims, wherein the access device is capable of having an oblong cross-section adjacent the distal end at least in the second configuration.

9. A system or access device according to any of the preceding claims, wherein the access device further comprises a skirt that is actuatable between the first and second configurations.

10. A system or access device according to Claim 9, further comprising an instrument having a working end and a proximal portion, the working end capable of being articulated from the proximal portion.

11. The access device or system of any of the preceding claims, wherein the access device comprises a proximal portion coupled with the distal portion, the proximal portion having a round cross-section.

12. The access device or system of any of the preceding claims, wherein the distal portion is capable of having an oblong cross-section.

13. The access device or system of any of the preceding claims, wherein the access device comprises a proximal portion pivotably coupled with the distal portion.

14. The access device or system of any of the preceding claims, wherein the access device comprises a proximal portion that is expandable.

15. A system according to Claims 5 and 6, wherein the prosthetic spinal disc implant mimics functionality of a natural intervertebral disc.

16. A system according to any of the preceding claims, further comprising:

a registration paddle for locating the interbody space, said registration paddle configured for insertion through the passage at least partially into the interbody space.

17. A system according to any of the preceding claims, further comprising:

a guide capable of being attached to the spine of the patient adjacent the interbody space.

18. The system of Claim 17, wherein the guide comprises a dovetail with which instruments may engage.

19. A system according to any of the preceding claims, further comprising:

means for visualizing, said means configured for insertion through at least a portion of the passage.

20. A surgical access device comprising a passage and a distal portion, the access device being actuatable between a first configuration wherein the passage has a first cross-sectional area at the distal portion suitable for insertion into the patient and a second configuration wherein the passage has an enlarged cross-sectional area at said distal portion, the access device being capable of providing access to an interbody space, the passage capable of having a replacement disc nucleus inserted therethrough to the interbody space.

21. A system for performing a minimally invasive replacement of at least a portion of a spinal disc, comprising:

the access device of Claim 20; and

an instrument capable of advancing the replacement disc nucleus through the passage.

22. The system of Claim 21, wherein the instrument is capable of advancing the replacement disc nucleus into the interbody space.

23. The system of either of Claims 21and 22 further comprising an instrument capable of removing at least a portion of a spinal disc.

24. A system for performing a multi-level procedure on a patient, comprising:

the access device of Claim 20; and

a replacement disc nucleus capable of being delivered through the access device to the interbody space.

25. The system of Claim 24, wherein the replacement disc nucleus is capable of being advanced into the interbody space.

26. A system or access device according to any of Claims 20 through 25, wherein the access device is capable of being inserted in order to provide access along an approach selected from the group consisting of a lateral approach, a posterior approach, a postero-lateral approach, a retro-peritoneal approach, an anterior approach and a transforaminal approach.

27. A system or access device according to any of Claims 20 through 26, wherein the access device is capable of having an oblong cross-section adjacent the distal end at least in the second configuration.

28. A system or access device according to any of Claims 20 through 27, wherein the access device further comprises a skirt that is actuatable between the first and second configurations.

29. A system or access device according to Claim 26, further comprising an instrument having a working end and a proximal portion, the working end capable of being articulated from the proximal portion.

30. A system or access device according to any of Claims 20 through 28, wherein the access device comprises a proximal portion coupled with the distal portion, the proximal portion having a round cross-section.

31. A system or access device according to any of Claims 20 through 30, wherein the distal portion is capable of having an oblong cross-section.

32. A system or access device according to any of Claims 20 through 31, wherein the access device comprises a proximal portion pivotably coupled with the distal portion.

33. A system or access device according to any of Claims 20through 32, wherein the access device comprises a proximal portion that is expandable.

34. A system according to any of Claims 20 through 33, further comprising:

an annulotomy tool for removing at least a portion of an annulus, said annulotomy tool configured for insertion through the passage; and

a disc evacuation tool for removing at least a portion of a nucleus, said disc evacuation tool configured for insertion through the passage.

35. A system according to any of Claims 20 through 34, wherein the replacement disc nucleus comprises an injectable material.

36. A system according to any of Claims 20 through 35, wherein the replacement disc nucleus comprises an expandable element.

37. A system according to Claim 36, wherein the expandable element comprises a bag in a collapsed configuration, wherein the bag may be inflated or allowed to expand.

38. A system according to Claim 37, wherein the bag can be inflated to an expanded configuration with a gas or liquid after insertion.

39. A system according to either of Claims 37or 38, further comprising:

an inflation tool for inflating the bag, said inflation tool configured for insertion through the passage.

40. A system according to Claim 37, wherein the bag comprises a self-expanding frame that assumes a collapsed state for insertion, and an expanded state once inserted.

41. A system or access device according to any of Claims 20through 40, wherein the distal end of the elongate body is shaped to conform to a contour of an anatomical structure near the interbody space.

42. A system or access device according to any of Claims 20through 41, wherein the distal end of the elongate body is configured for insertion into an annulus.

43. A system or access device according to Claim 42, wherein the elongate body is configured to enlarge a hole in the annulus when articulating to the expanded configuration.

44. A system according to any of Claims 20through 43, further comprising a viewing element configured for insertion into the passage.

45. A system for stabilizing at least two adjacent vertebrae of the spine of a patient, said system comprising:

an access device comprising a passage and a distal portion, the access device being actuatable between a first configuration wherein the passage has a first cross-sectional area at the distal portion suitable for insertion into the patient and a second configuration wherein the passage has an enlarged cross-sectional area at said distal portion, the access device being capable of providing access to at least one of the two adjacent vertebrae; and

a motion preserving, stabilization device, wherein the stabilization device is configured for insertion through the passage and attachment between the at least two adjacent vertebrae.

46. The system of Claim 45, further comprising:

a bone probe for forming a hole in one of the at least two adjacent vertebrae, the bone probe configured for insertion through the passage; and

a tap for creating a tapped hole portion of the hole, the tap configured for insertion through the passage.

47. The system of either of Claims 45 or 46, wherein the access device is capable of being inserted in order to provide access along an approach selected from the group consisting of a lateral approach, a posterior approach, a postero-lateral approach, a retro-peritoneal approach, an anterior approach and a transforaminal approach.

48. A system according to any of Claims 45 through 47, wherein the access device is capable of having an oblong cross-section adjacent the distal end at least in the second configuration.

49. A system according to any of Claims 45 through 48, wherein the access device further comprises a skirt that is actuatable between the first and second configurations.

50. A system according to any of Claims 45 through 49, wherein the access device comprises a proximal portion coupled with the distal portion, the proximal portion having a round cross-section.

51. A system according to any of Claims 45 through 50, wherein the distal portion is capable of having an oblong cross-section.

52. A system according to any of Claims 45 through 51, wherein the access device comprises a proximal portion pivotably coupled with the distal portion.

53. A system according to any of Claims 45 through 52, wherein the access device comprises a proximal portion that is expandable.

54. A system according to any of Claims 45 through 53, wherein the stabilization device comprises a fastener and a connecting element.

55. A system according to any of Claims 45through 54, wherein the stabilization device further comprises a clamping element for coupling the fastener to the connecting element.

56. A system according to any of Claims 45 through 55, wherein the connecting element comprises a flexible material and is sized to span a distance between at least the two adjacent vertebrae.

57. A system according to any of Claims 45 through 56, wherein the connecting element tends to substantially return to a pre-deformed state when deformed.

58. A system according to any of Claims 45 through 57, wherein the connecting element comprises a link rod assembly connected between the two adjacent vertebrae, said link rod assembly comprising at least one jointed member configured to preserve motion between the two adjacent vertebrae.

59. A system according to any of Claims 45 through 58, wherein the stabilization device comprises a facet joint replacement device.

60. A system for fixing at least two adjacent vertebrae of the spine of a patient, said system comprising:

an access device comprising a passage and a distal portion, the access device being actuatable between a first configuration wherein the passage has a first cross-sectional area at the distal portion suitable for insertion into the patient and a second configuration wherein the passage has an enlarged cross-sectional area at said distal portion, the access device being capable of providing access to at least one of the two adjacent vertebrae; and

a first fastener for transfacet fixation, wherein the first fastener is configured for insertion through the passage.

61. The system of Claim 60, further comprising:

a boring tool for creating a tunnel through the at least two adjacent vertebrae, said boring tool configured for insertion through the passage.

62. The system of either of Claims 60 or 61, wherein the access device is capable of being inserted in order to provide access along an approach selected from the group consisting of a lateral approach, a posterior approach, a postero-lateral approach, a retro-peritoneal approach, an anterior approach and a transforaminal approach.

63. A system according to any of Claims 60 through 62, wherein the access device is capable of having an oblong cross-section adjacent the distal end at least in the second configuration.

64. A system according to any of Claims 60 through 63, wherein the access device further comprises a skirt that is actuatable between the first and second configurations.

65. A system according to any of Claims 60 through 64, wherein the access device comprises a proximal portion coupled with the distal portion, the proximal portion having a round cross-section.

66. A system according to any of Claims 60 through 65, wherein the distal portion is capable of having an oblong cross-section.

67. A system according to any of Claims 60 through 66, wherein the access device comprises a proximal portion pivotably coupled with the distal portion.

68. A system according to any of Claims 60 through 67, wherein the access device comprises a proximal portion that is expandable.

69. A system according to any of Claims 60 through 68, wherein the first fastener is configured for transfacet pedicle screw fixation.

70. A system according to any of Claims 60through 69, wherein the first fastener is configured for translaminar facet screw fixation.

71. A system according to any of Claims 60 through 70, further comprising:

a second fastener for transfacet fixation, wherein the second fastener is configured for insertion through the passage.

72. Use of any of the access devices or systems of any of the preceding claims in spinal surgery.

73. A method of replacing an intervertebral disc in an interbody space of a spine of a patient, comprising:

inserting an access device through an incision in a skin of the patient;

expanding said access device from a first configuration to a second configuration, the second configuration having an enlarged cross-sectional area at a distal portion of said access device such that the distal portion extends across at least a portion of the interbody space; and

delivering a prosthetic spinal disc implant through the access device.

74. The method of Claim 73, wherein inserting further comprises inserting the access device along a lateral approach.

75. The method of Claim 73, wherein inserting further comprises inserting the access device along a posterolateral approach.

76. The method of Claim 73, wherein the prosthetic spinal disc implant mimics functionality of a natural intervertebral disc.

77. The method of Claim 73, wherein said access device is a first access device, and further comprising inserting a second access device through an incision in a skin of the patient, and delivering an additional prosthetic spinal disc implant through the second access device.

78. The method of Claim 73, further comprising, prior to delivering the prosthetic spinal disc implant, preparing the interbody space to receive said implant through said access device.

79. The method of Claim 78, wherein the step of preparing the interbody space further comprises locating the interbody space by inserting a registration paddle through said access device at least partially into said interbody space.

80. The method of Claim 78, wherein the step of preparing the interbody space further comprises affixing a guide adjacent said interbody space.

81. The method of Claim 80, wherein the guide comprises a dovetail with which instruments may engage.

82. The method of Claim 80, wherein the step of preparing further comprises milling a path in the interbody space using a template in said guide.

83. The method of Claim 73, further comprising providing visualization into at least a portion of the access device.

84. A method of replacing a portion of a disc of a patient, the disc having an annulus and a nucleus, comprising:

inserting an access device through an incision in the skin of the patient generally postero-laterally and advancing the access device until a distal portion thereof is located adjacent the spine, said access device being inserted in a first configuration having a first cross-sectional area at the distal portion thereof;

configuring said access device such that the distal portion thereof is enlarged from the first configuration to a second configuration wherein the distal portion extends across at least a portion of the disc;

advancing an annulotomy tool through the access device to the intervertebral space;

forming an aperture in the annulus;

advancing a disc evacuation tool through the access device and through the aperture;

removing at least a portion of the nucleus through the access device to at least partially evacuate the intervertebral space; and

delivering a replacement disc nucleus into the partially evacuated intervertebral space through the access device.

85. The method of Claim 84, wherein the replacement disc nucleus comprises an injectable material.

86. The method of Claim 85, wherein the injectable material is chosen from a group comprising: hydrogels, thermoplastic elastomers, and proteinaceous biopolymers.

87. The method of Claim 84, wherein the replacement disc nucleus comprises an expandable element.

88. The method of Claim 87, wherein the expandable element comprises:

a bag in a collapsed configuration, wherein the bag may be inflated or allowed to expand.

89. The method of Claim 88, wherein the replacement disc nucleus further comprises a biocompatible material, which is injected into the bag in an expanded configuration.

90. The method of Claim 89, wherein the biocompatible material includes tissues, cells, or extracellular matrix components.

91. The method of Claim 89, wherein the biocompatible material includes autograft nucleus pulposus, allograft nucleus pulposus or xenograft nucleus pulposus.

92. The method of Claim 89, wherein the biocompatible material includes morselized nucleus or annulus from the disc.

93. The method of Claim 88, wherein the bag can be inflated to an expanded configuration with a gas or liquid after insertion.

94. The method of Claim 93, wherein a tool is inserted through the access device in order to inflate the bag.

95. The method of Claim 88, wherein the bag comprises a self-expanding frame that assumes a collapsed state for insertion, and an expanded state once inserted.

96. The method of Claim 95, wherein the self-expanding frame is composed of a shape-memory material.

97. The method of Claim 87, wherein the expandable element comprises:

a hydrogel core configured to expand from a dehydrated state to a hydrated state, the hydrogel core being configured to have a dehydrated shape in the dehydrated state that facilitates insertion of the replacement disc nucleus through an opening in an annulus fibrosus and being generally different from a hydrated shape of the hydrogel core in the hydrated state,

wherein the hydrogel core is surrounded by a constraining jacket, the constraining jacket being flexible but substantially inelastic.

98. The method of Claim 97, wherein the hydrogel core comprises a keratin hydrogel.

99. The method of Claim 97, wherein the constraining jacket is porous enough to allow the hydrogel core to interact with bodily fluids.

100. The method of Claim 99, wherein the hydrogel core is dehydrated prior to insertion.

101. The method of Claim 84, wherein the replacement disc nucleus comprises:

an ellipsoidal body having a convex top side for contracting and articulating with an end-plate cartilage of a top vertebrae and a convex bottom side for an immobile contact with a bottom vertebrae;

said convex top side having a dome crest that exceeds a dome crest of said convex bottom side by a factor of approximately three; and

a peg extending from said bottom side of the ellipsoidal body and providing for a pinning action with respect to said bottom vertebrae.

102. The method of Claim 84, wherein the replacement disc nucleus comprises disc cells and a biodegradable substrate.

103. The method of Claim 102, wherein the biodegradable substrate is bioactive.

104. A method of treating the spine of a patient, comprising:

inserting an access device through a minimally invasive incision in the skin of the patient;

advancing the access device until a distal portion thereof is located adjacent the spine;

expanding said access device from a first configuration to a second configuration, the second configuration having an enlarged cross-sectional area at the distal portion thereof such that the distal portion extends across at least a portion of a disc;

delivering a replacement disc nucleus into an intervertebral space through the access device.

105.A device for providing access to a surgical location within a patient, said device comprising:

an elongate body having a proximal end, a distal end, and a passage extending therebetween, the elongate body defining a length between the proximal and distal ends such that the proximal end can be positioned outside the patient and the distal end can be positioned inside the patient adjacent the surgical location, the distal end being shaped to conform to a contour of an anatomical structure near the surgical location; and

wherein the elongate body is actuatable between a first configuration sized for insertion into the patient and a second configuration wherein the cross-sectional area of said passage at a first location is greater than the cross-sectional area of said passage at a second location, wherein the first location is distal to the second location.

106.A system for replacing a portion of a disc having a nucleus and an annulus, comprising

the access device of Claim 105;

an annulotomy tool for forming an aperture in the annulus through the access device; and

a disc evacuation tool for removing at least a portion of the nucleus through the access device.

107.A device for accessing an intervertebral disc of a patient having a nucleus and an annulus, said device comprising:

an elongate body having a proximal end, a distal end, and a passage extending therebetween, the elongate body defining a length between the proximal and distal ends such that the proximal end can be positioned outside the patient and the distal end can be advanced inside the patient and into the annulus; and

wherein the elongate body is actuatable between a first configuration sized for advancement to spine and a second configuration wherein the cross-sectional area of said passage at a first location is greater than the cross-sectional area of said passage at a second location, wherein the first location is distal to the second location.

108.The device of Claim 107, wherein the distal end can be further advanced through the annulus.

109.The device of Claim 107, wherein the elongate body actuating between a first configuration and a second configuration enlarges a hole in the annulus.

110.A device for accessing an intervertebral disc of a patient having a nucleus and an annulus, said device comprising:

an elongate body having a proximal end, a distal end, a passage extending therebetween, and a viewing element aperture located near the distal end, the elongate body defining a length between the proximal and distal ends such when the distal end is advanced into the patient to the annulus, the proximal end is positioned outside the patient; and

a viewing element extending through the aperture into the passage.

111.A method of stabilizing at least two adjacent vertebrae of the spine of a patient, comprising:

inserting an access device through an incision in the skin of the patient generally posteriorly and advancing the access device until a distal portion thereof is located adjacent the spine, said access device being inserted in a first configuration having a first cross-sectional area at the distal portion thereof;

configuring said access device such that the distal portion thereof is enlarged from the first configuration to a second configuration wherein the distal portion is large enough to extend across at least a portion of the adjacent vertebrae;

advancing a bone probe through the access device to one of the two adjacent vertebrae;

forming a hole in one of the two adjacent vertebrae;

advancing a tap through the access device to one of the two adjacent vertebrae;

advancing the tap into at least a portion of the hole to create a tapped hole portion;

delivering a fastener through the access device to the tapped hole portion;

delivering a connecting element through the access device; and

coupling said connecting element to the fastener in a manner that permits motion between the adjacent vertebrae.

112.The method of Claim 111, wherein coupling the connecting element to the fastener further comprises:

delivering a clamping element through the access device; and

coupling said clamping element to the fastener.

113.The method of Claim 111, wherein inserting the access device further comprises inserting the access device generally postero-laterally.

114.The method of Claim 111, wherein the connecting element selectively permits one of the two adjacent vertebrae to move away the other of the two adjacent vertebrae.

115.The method of Claim 111, wherein the connecting element selectively permits one of the two adjacent vertebrae to move toward the other of the two adjacent vertebrae.

116. The method of Claim 111, further comprising crimping said connecting element member between said clamping element and said fastener.

117. The method of Claim 111, wherein the connecting element comprises a flexible material and is sized to span a distance between at least the two adjacent vertebrae,

118. The method of Claim 111, wherein the connecting element comprises a material selected from the group consisting of polymers, superelastic metals, superelastic alloys, and resorbable materials.

119. The method of Claim 118, wherein the material is nitinol.

120. The method of Claim 111, wherein the connecting element tends to substantially return to a pre-deformed state when deformed.

121. The method of Claim 111, wherein the connecting element comprises a link rod assembly connected between the two adjacent vertebrae, said link rod assembly comprising at least one jointed member configured to preserve motion between the two adjacent vertebrae.

122. The method of Claim 111, wherein the connecting element comprises a body extending in a direction of alignment, the body being resiliently compressible under forces acting in the alignment direction from a first elongate configuration to a second elongate configuration and reverting to the first elongate configuration spontaneously after the forces is removed.

123. The method of Claim 122, wherein the body comprises a leaf spring having geometrically shaped walls defining an opening.

124. The method of Claim 122, wherein the fastener comprises a member adapted to be anchored to spinous processes of one of the two adjacent vertebrae.

125. The method of Claim 111, wherein the connecting element comprises an artificial ligament.

126. The method of Claim 125, wherein the artificial ligament comprises at least one of a synthetic resorbable material, a natural resorbable material, or a nonresorbable material.

127. A method of treating two adjacent vertebrae in a spine of a patient, comprising:

inserting an access device through a minimally invasive incision in the skin of the patient;

advancing the access device until a distal portion thereof is located adjacent the spine;

expanding said access device from a first configuration to a second configuration, the second configuration having an enlarged cross-sectional area at the distal portion thereof such that the distal portion extends across at least a portion of the two adjacent vertebrae;

delivering a motion preserving, stabilization device to a location between the two adjacent vertebrae through the access device.

128.The method of Claim 127, wherein the stabilization device comprises a facet joint replacement device.

129.A method of treating a spine of a patient, comprising:

inserting an access device through a minimally invasive incision in the skin of the patient;

advancing the access device until a distal portion thereof is located adjacent the spine;

expanding said access device from a first configuration to a second configuration, the second configuration having an enlarged cross-sectional area at the distal portion thereof such that the distal portion extends across at least one of two adjacent vertebrae;

delivering a stabilization device through the access device to a location between the two adjacent vertebrae, the stabilization device being configured to preserve motion between the two adjacent vertebrae.

130.The method of Claim 129, wherein inserting further comprises inserting along a generally posterior approach.

131.The method of Claim 129, wherein the stabilization device selectively permits one of the two adjacent vertebrae to move away the other of the two adjacent vertebrae.

132.The method of Claim 129, wherein the stabilization device selectively permits one of the two adjacent vertebrae to move toward the other of the two adjacent vertebrae.

133.The method of Claim 129, wherein the stabilization device comprises:

an elongate member sized to span a distance between at least the two adjacent vertebrae, said elongate member being at least partially made from a flexible material;

a plurality of fasteners securing said elongate member to each of said at least two adjacent vertebrae, each of said fasteners having an elongate member receiving portion; and

a plurality of coupling elements each attachable to a corresponding one of said plurality of fasteners;

wherein each of said coupling elements includes means for crimping said elongate member between said coupling element and said corresponding fastener on at least two locations along said elongate member, whereby said elongate member stabilizes the adjacent vertebrae while preserving motion between the adjacent vertebrae.

134.The method of Claim 133, wherein the elongate member comprises a material selected from the group consisting of polymers, superelastic metals and alloys, and resorbable synthetic materials.

135.The method of Claim 134, wherein the material is nitinol.

136.The method of Claim 133, wherein the elongate member tends to substantially return to a pre-deformed state when deformed.

137.The method of Claim 133, wherein the elongate member is relatively inflexible along its elongated axis.

138.The method of Claim 129, wherein the stabilization device comprises a link rod connected between the two adjacent vertebrae, which link rod comprises at least one jointed member configured to preserve motion between the adjacent vertebrae.

139.The method of Claim 129, wherein the stabilization device comprises two fasteners adapted to be fastened to the adjacent vertebra and having a body extending in a direction of alignment of the fasteners, the body being resiliently compressible under forces acting in the alignment direction from a first configuration to a second configuration and reverting to the first configuration spontaneously after the forces is removed.

140.The method of Claim 139, wherein the body comprises a leaf spring having geometrically shaped walls defining an opening.

141.The method of Claim 139, wherein the two fasteners comprise two anchor members adapted to be anchored to spinous processes of the two adjacent vertebrae.

142.The method of Claim 129, wherein the stabilization device comprises an artificial ligament, and at least one fastener engaged to one of the two adjacent vertebrae attaching the artificial ligament to the one of the two adjacent vertebrae.

143.The method of Claim 142, wherein the artificial ligament comprises at least one of a synthetic resorbable material, a natural resorbable material, or a nonresorbable material.

144.The method of Claim 129, wherein the stabilization device comprises a cushioning member between a pair of endplates.

145.The method of Claim 144, wherein the stabilization device comprises a facet joint replacement device.

146.The method of Claim 144, wherein the cushioning member comprises an elastomer.

147. The method of Claim 144, wherein the cushioning member comprises an elastomer.

148. The method of Claim 144, wherein the cushioning member comprises a polymeric urethane.

149. A system configured to apply a dynamic stabilization device between two adjacent vertebrae, comprising:

an access device having a first configuration having a first cross-sectional area at the distal portion thereof for insertion, said access device having a second configuration wherein the distal portion thereof is enlarged to extend across at least one of the two adjacent vertebrae, the access device configured to permit the dynamic stabilization device to be advanced therethrough;

a bone probe configured to be advanced through the access device to form a hole in one of the two adjacent vertebrae; and

a tap configured to be advanced through the access device to thread the hole to create a tapped hole.

150. A method of fixing adjoining vertebrae of the spine of a patient, comprising:

inserting into said patient an access device to a surgical location adjacent the spine with said access device in a first configuration having a first cross-sectional area at a distal portion thereof;

actuating said access device to a second configuration having an enlarged cross-sectional area at said distal portion thereof;

delivering a first fastener through the access device to the surgical location; and

advancing said first fastener through a first vertebra and into a second vertebra.

151. The method of Claim 150, wherein the access device is inserted via a generally posterior approach.

152. The method of Claim 150, wherein the access device is inserted via a postero-lateral approach.

153. The method of Claim 150, further comprising the introduction of a boring tool to the surgical location through the access device and advancing said boring tool to create a tunnel through the bone prior to delivering said first fastener.

154. The method of Claim 150, wherein the surgical location is scored prior delivering the fastener or boring through the bone.

155. The method of Claim 150, wherein the method of fixation is transfacet pedicle screw fixation.

156. The method of Claim 150, wherein the method of fixation is translaminar facet screw fixation.

157.The method of Claim 150, further comprising delivering through an access device a second fastener to a second surgical location at the spine and advancing the fastener through the first vertebra and into the second vertebra, said fastener substantially preventing movement of the first vertebra relative to the second vertebra.

158.The method of Claim 157, further comprising prior to delivering said second fastener, introducing a boring tool to said second surgical location through the access device and advancing said boring tool to create a tunnel through the bone.

159.The method of Claim 157, wherein said second fastener is delivered through the same access device used to deliver said first fastener.

160.The method of Claim 157, wherein said second fastener is delivered through a second access device.

161.The method of Claim 157, wherein said second fastener is delivered through a cannula.

162.The method of Claim 157, wherein said second surgical location is scored prior delivering said second fastener or boring through the bone

163.A method of treating a spine of a patient, comprising:

inserting an access device into said patient to a surgical location adjacent the spine with said access device in a first configuration having a first cross-sectional area at a distal portion thereof;

actuating said access device to a second configuration having an enlarged cross-sectional area at said distal portion thereof; and

fastening through a first vertebra and into a second vertebra one or more fasteners delivered through said access device, said one or more fasteners providing a transfacet fixation method substantially preventing movement of the first vertebra relative to the second vertebra.

164.The method of Claim 163, wherein the access device is inserted via a generally posterior approach.

165.The method of Claim 163, wherein the access device is inserted via a postero-lateral approach.

166.The method of Claim 163, wherein a single access device is used to approach the surgical location adjacent the spine.

167.The method of Claim 163, wherein multiple access devices are used to approach the surgical location adjacent the spine.

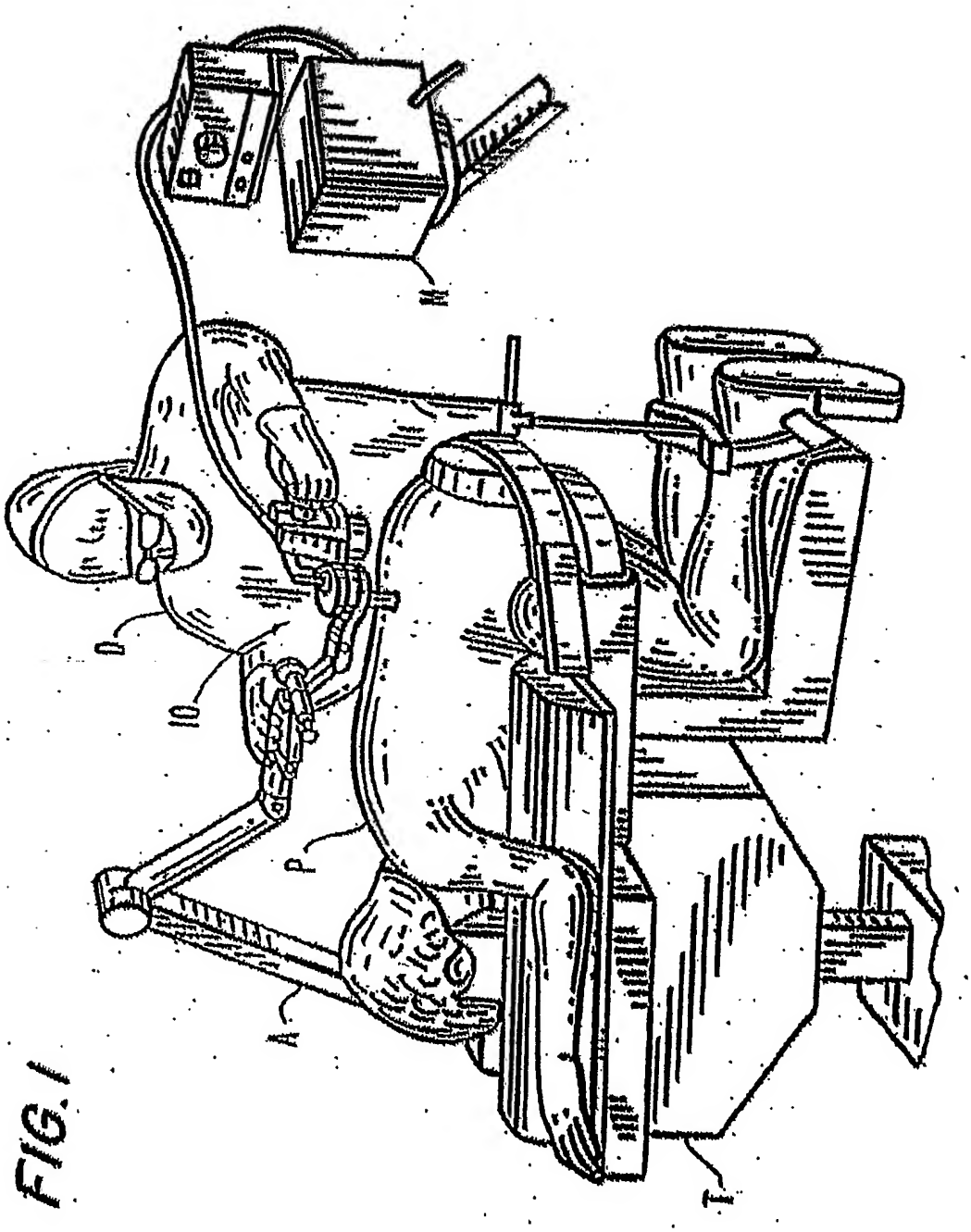


FIG. 1

FIG. 2

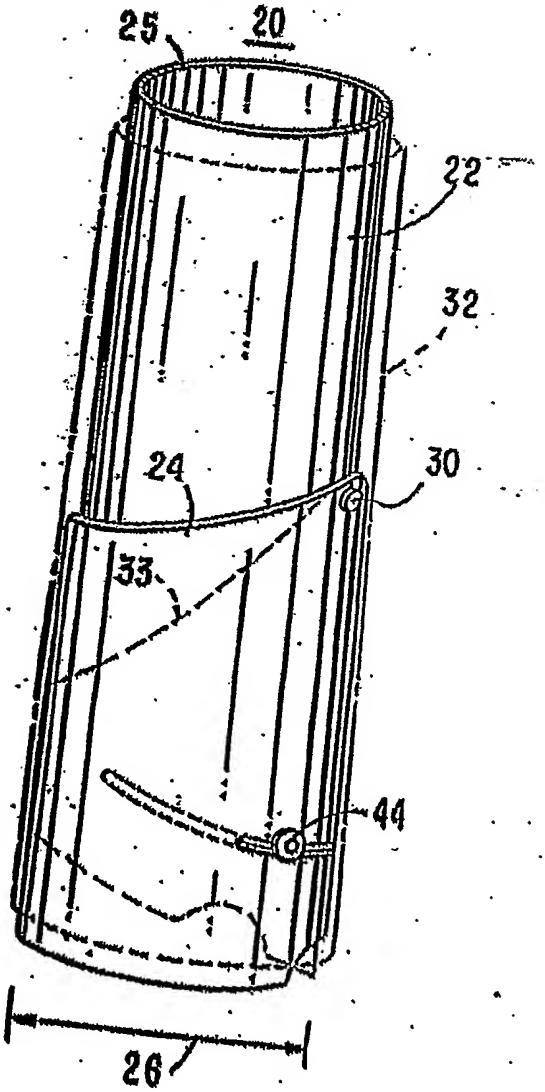
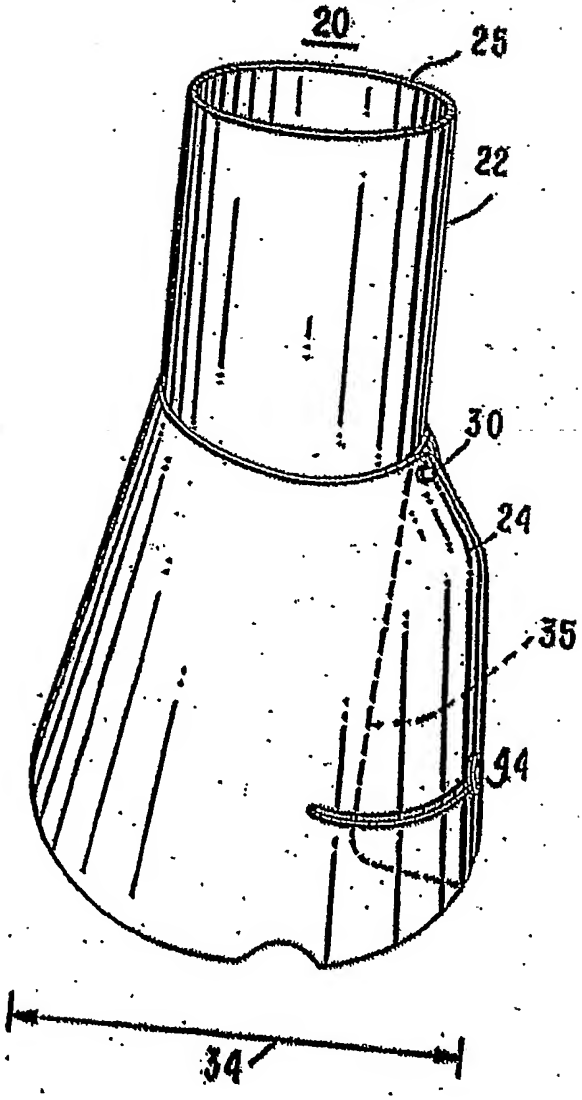


FIG. 3



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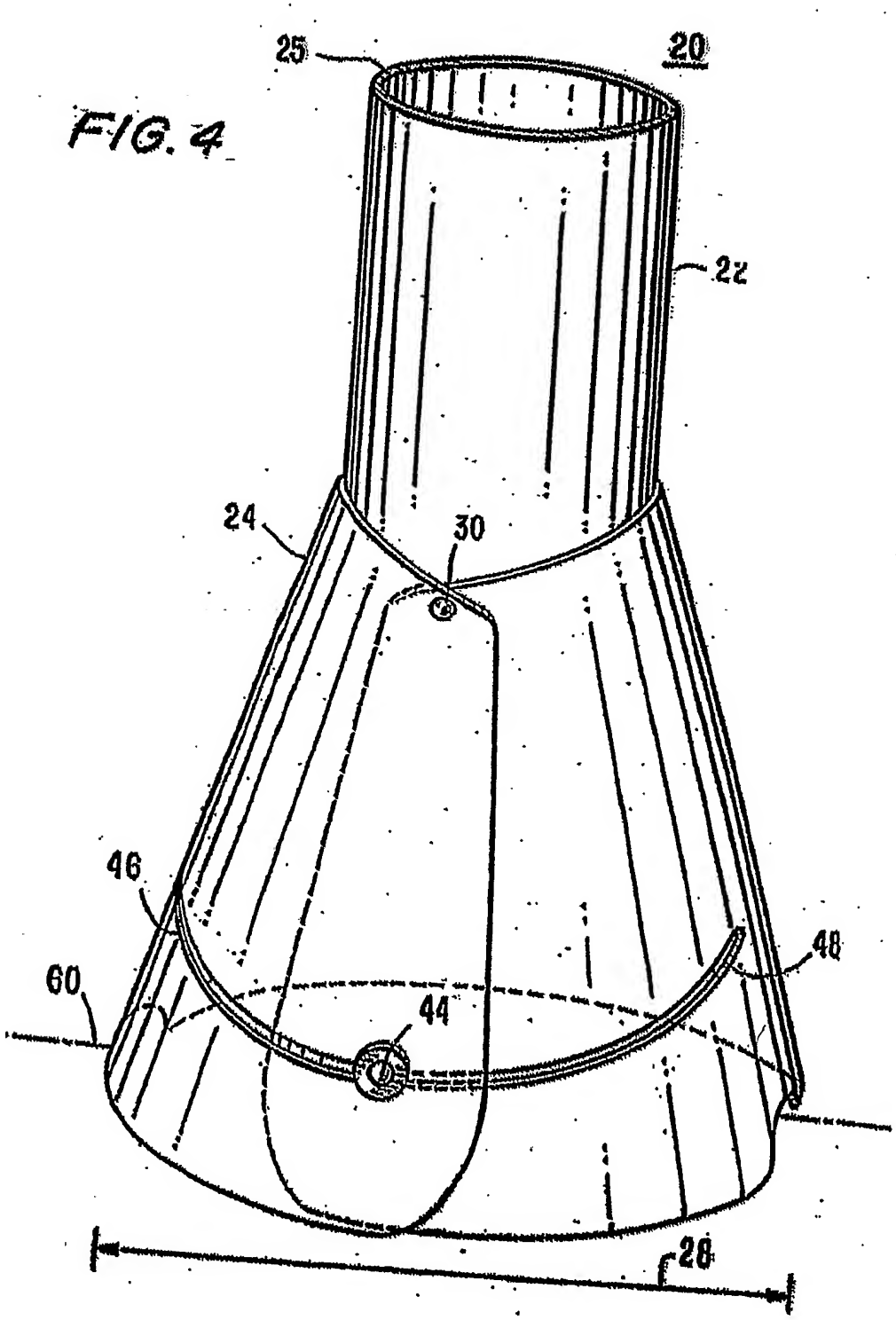


FIG. 6

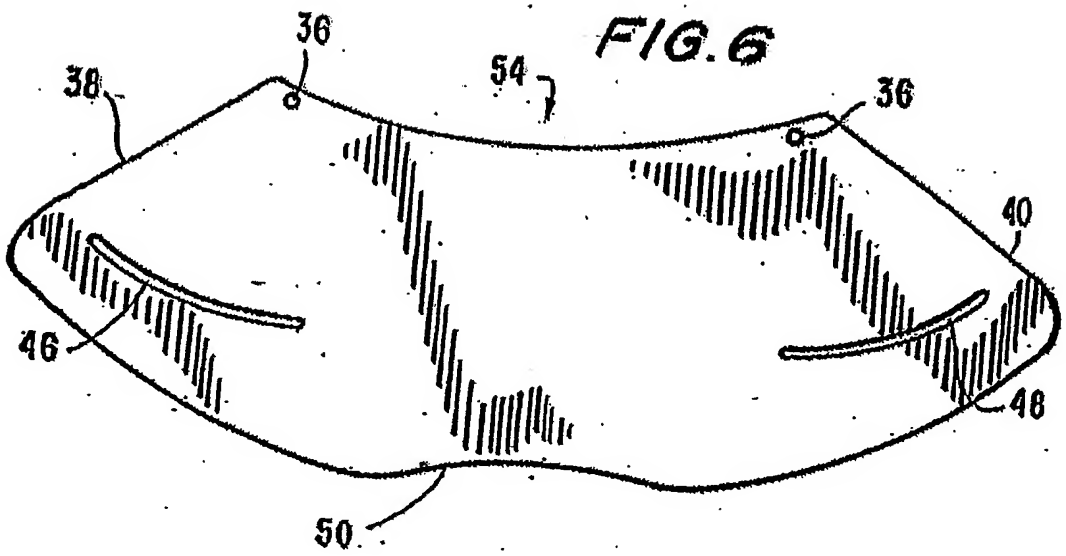
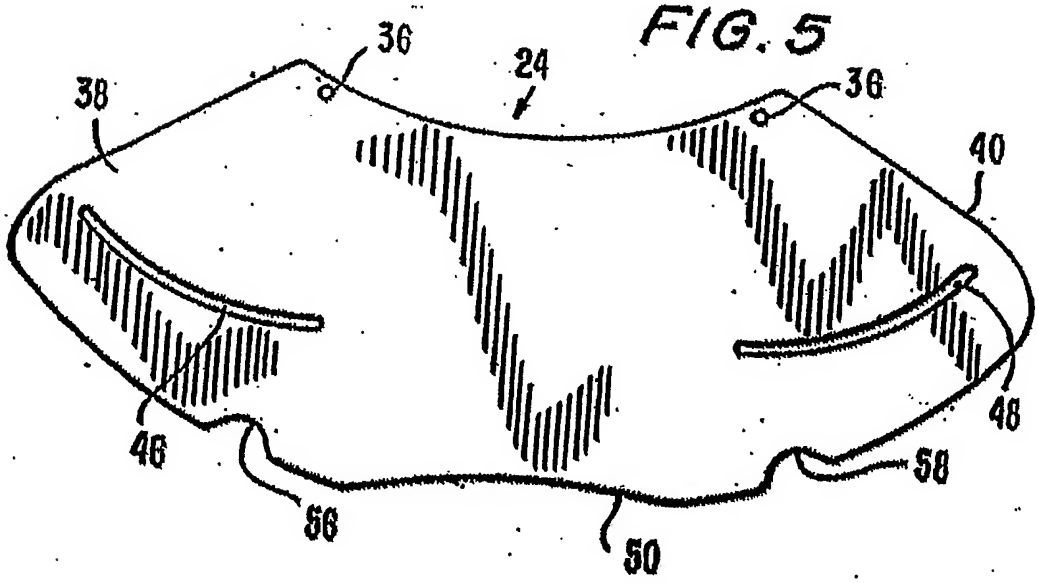


FIG. 5



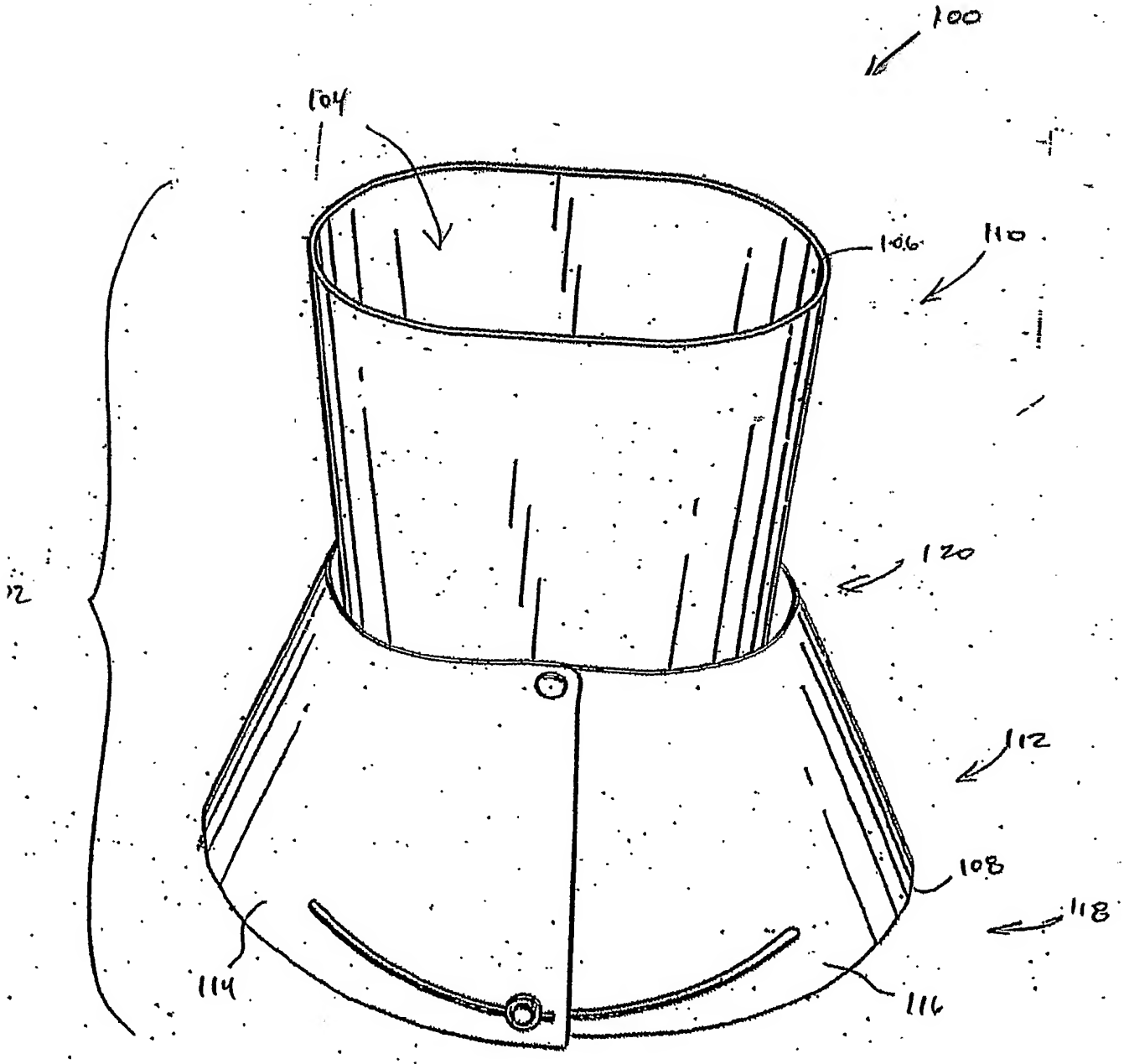


FIG 7

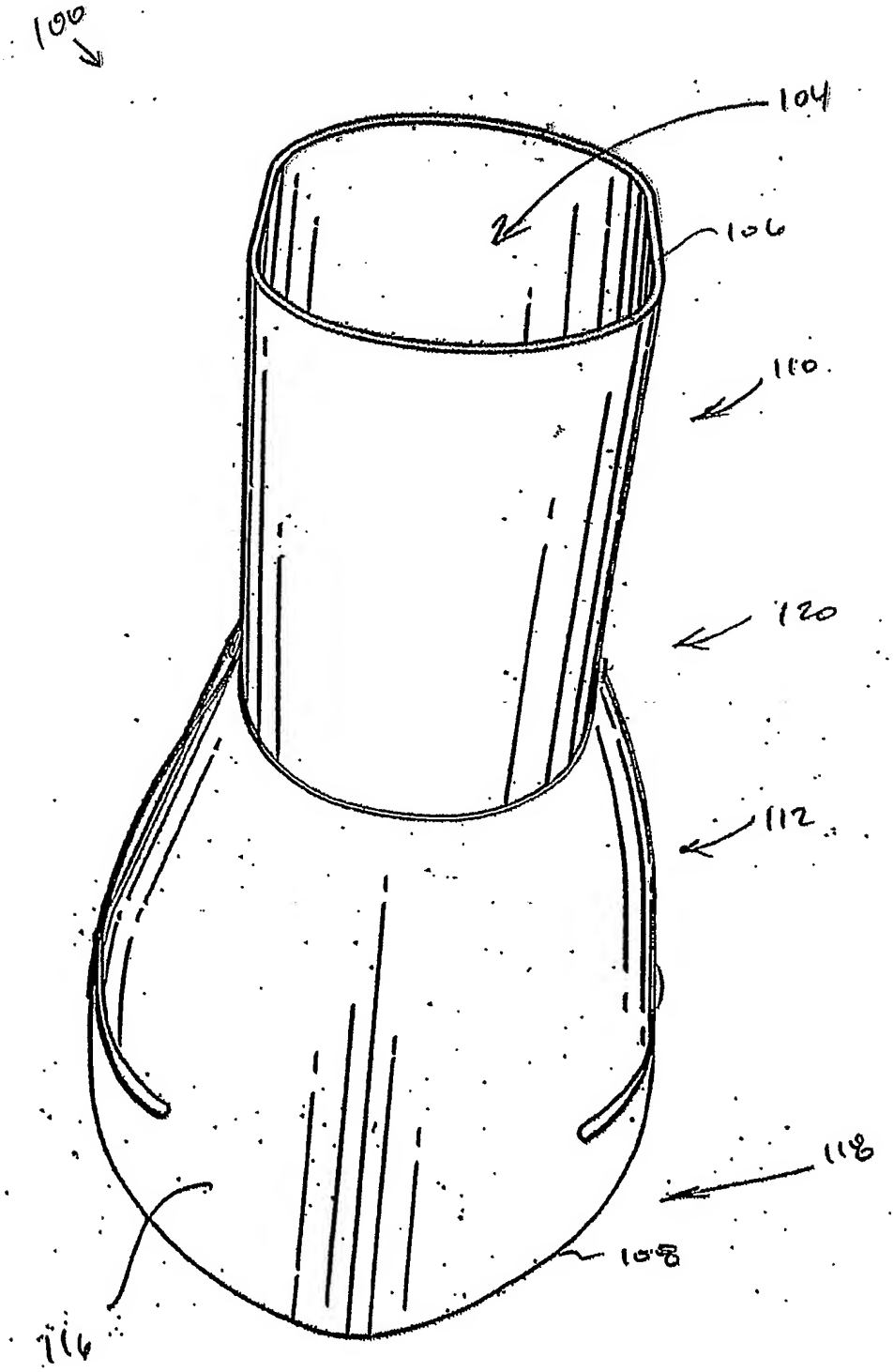


FIG 8

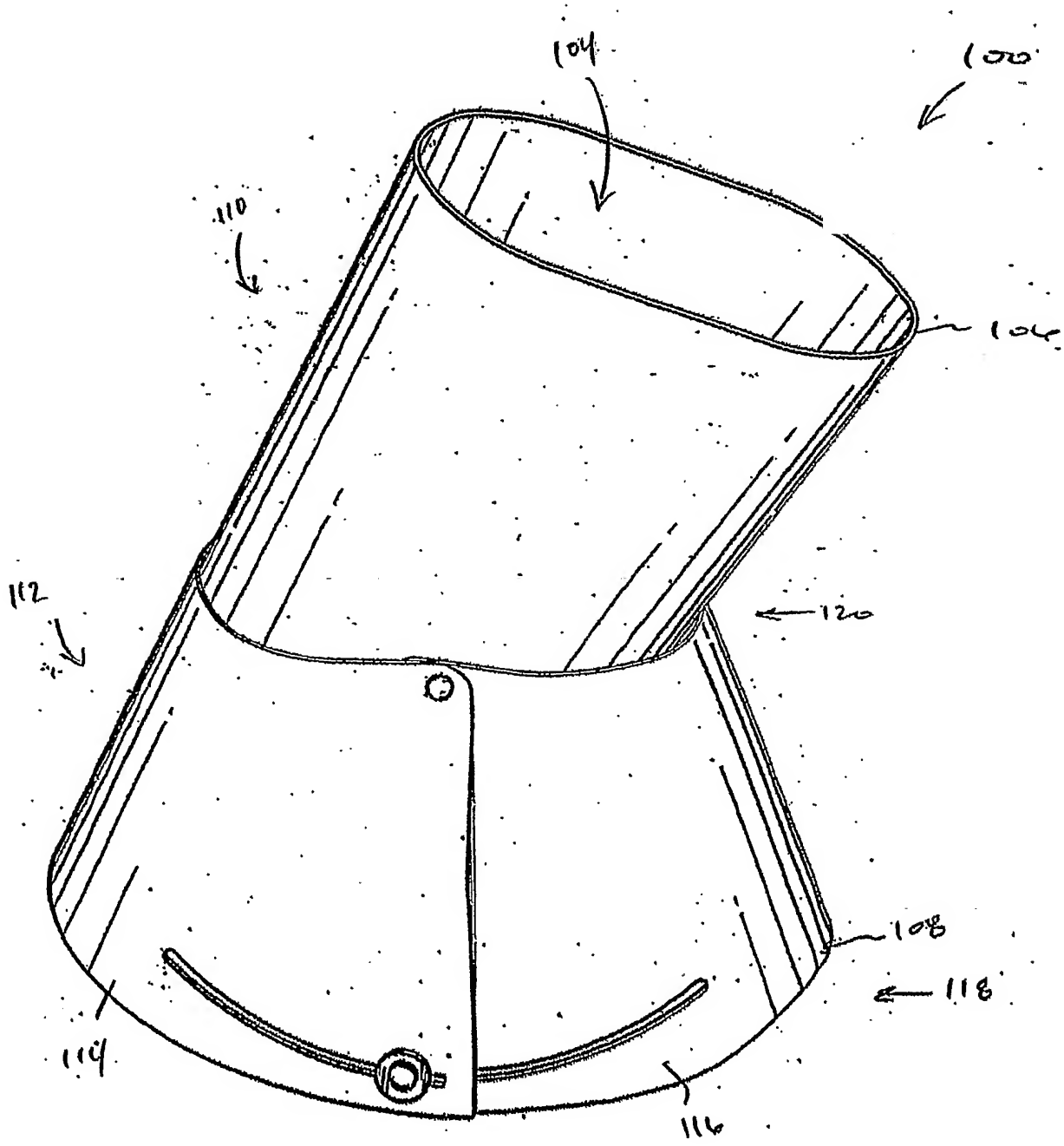


FIG 9

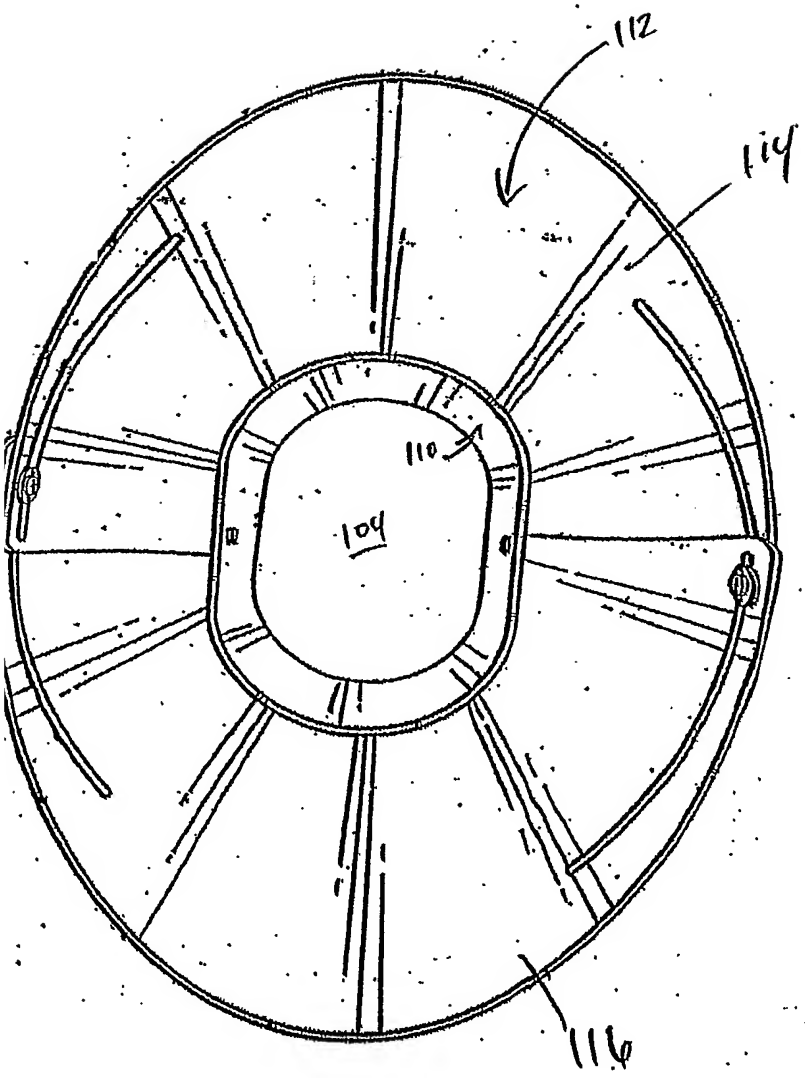


FIG 10

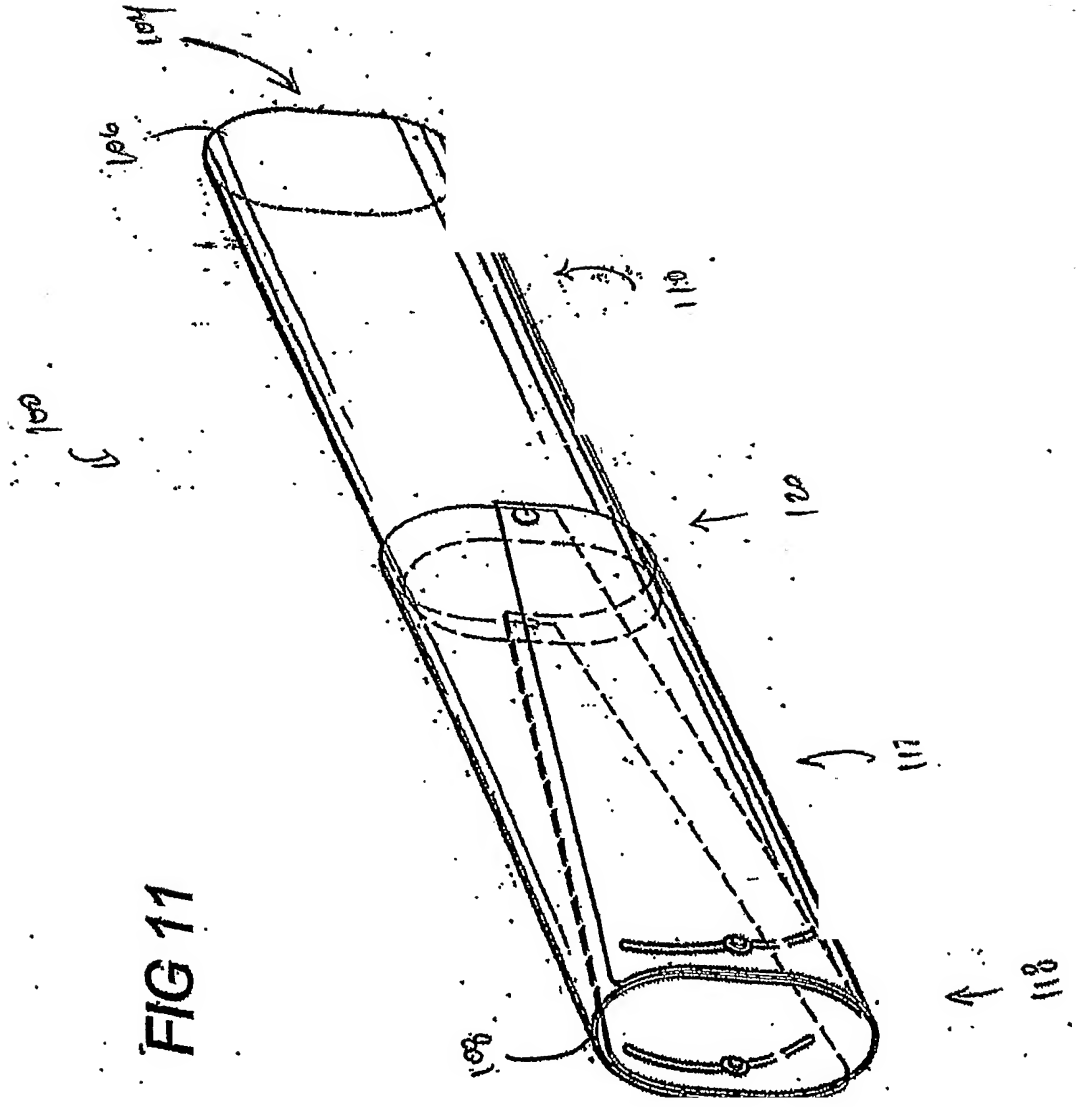


FIG 11

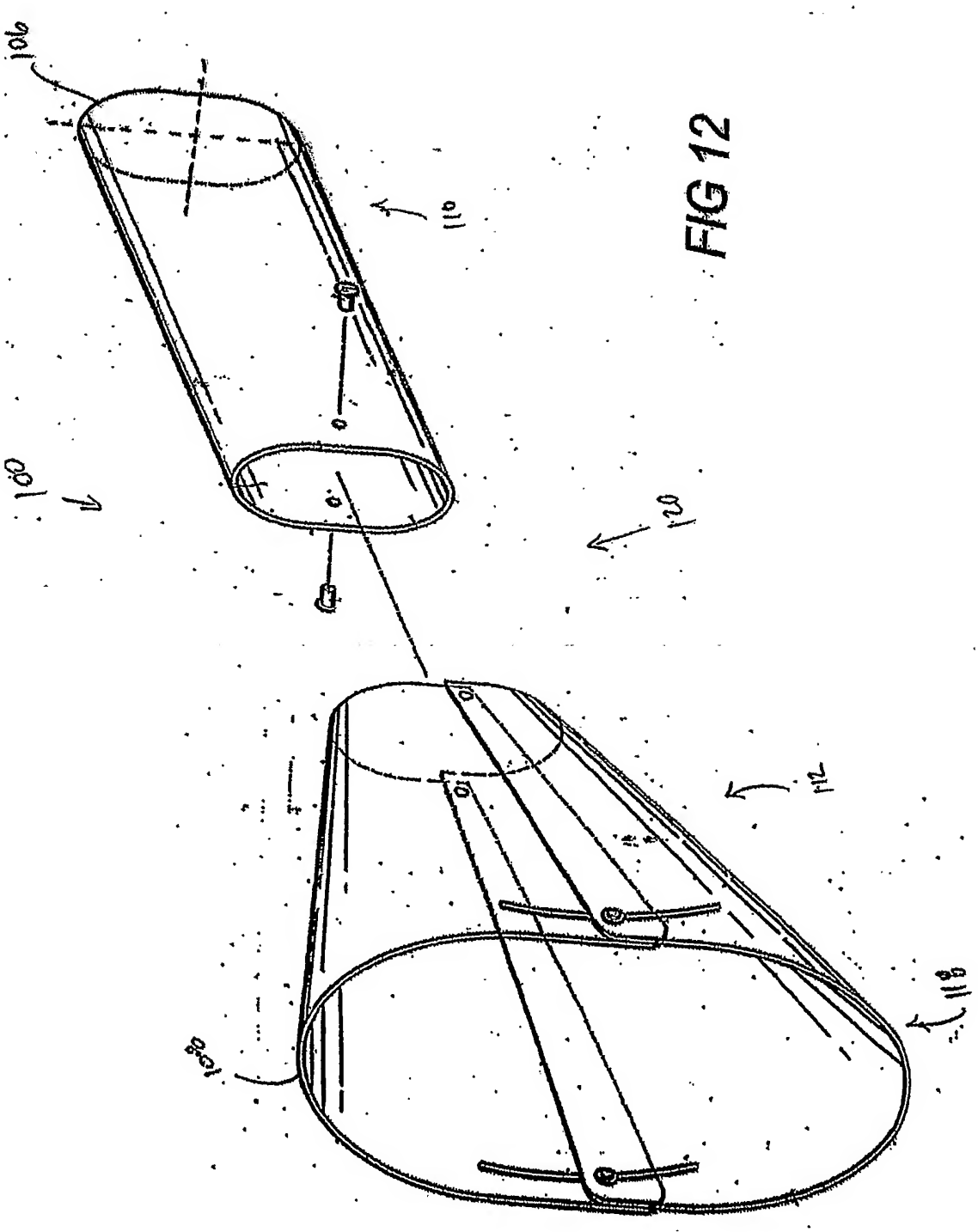
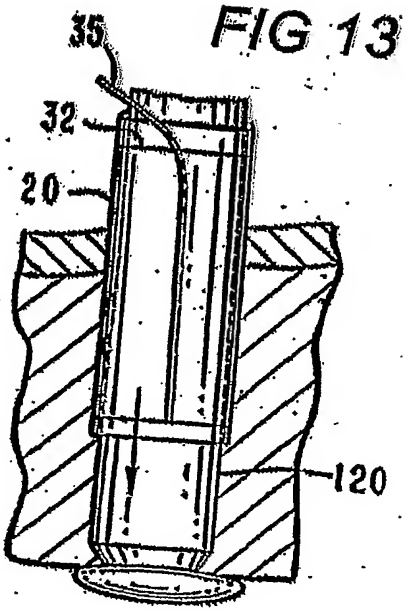


FIG 12

FIG 13



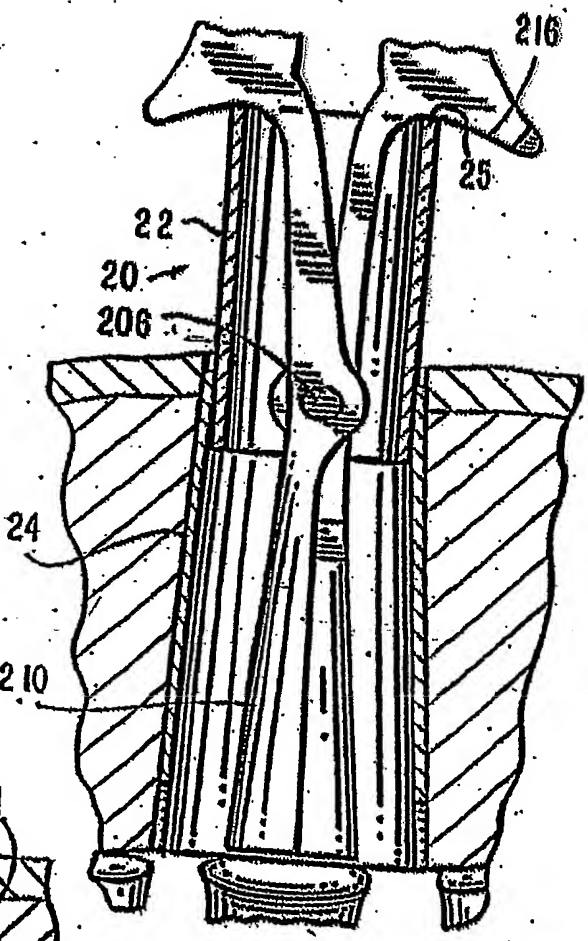


FIG 16

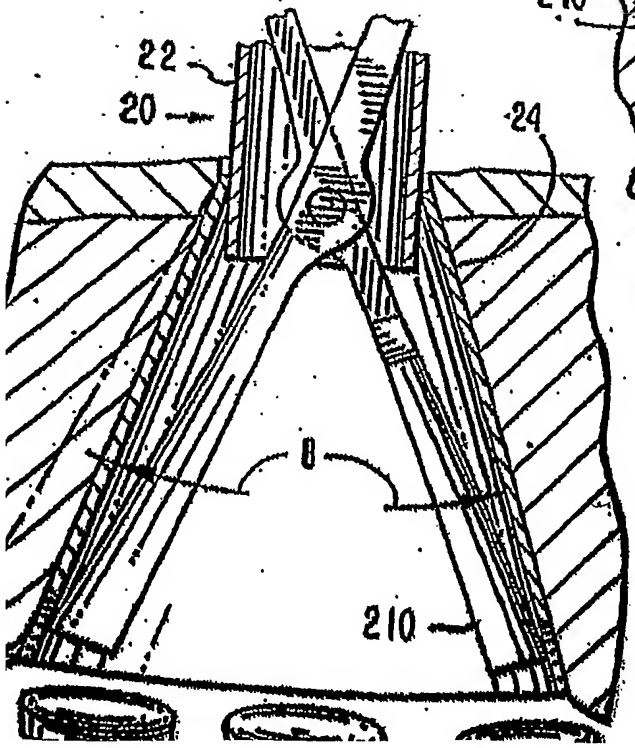


FIG 17

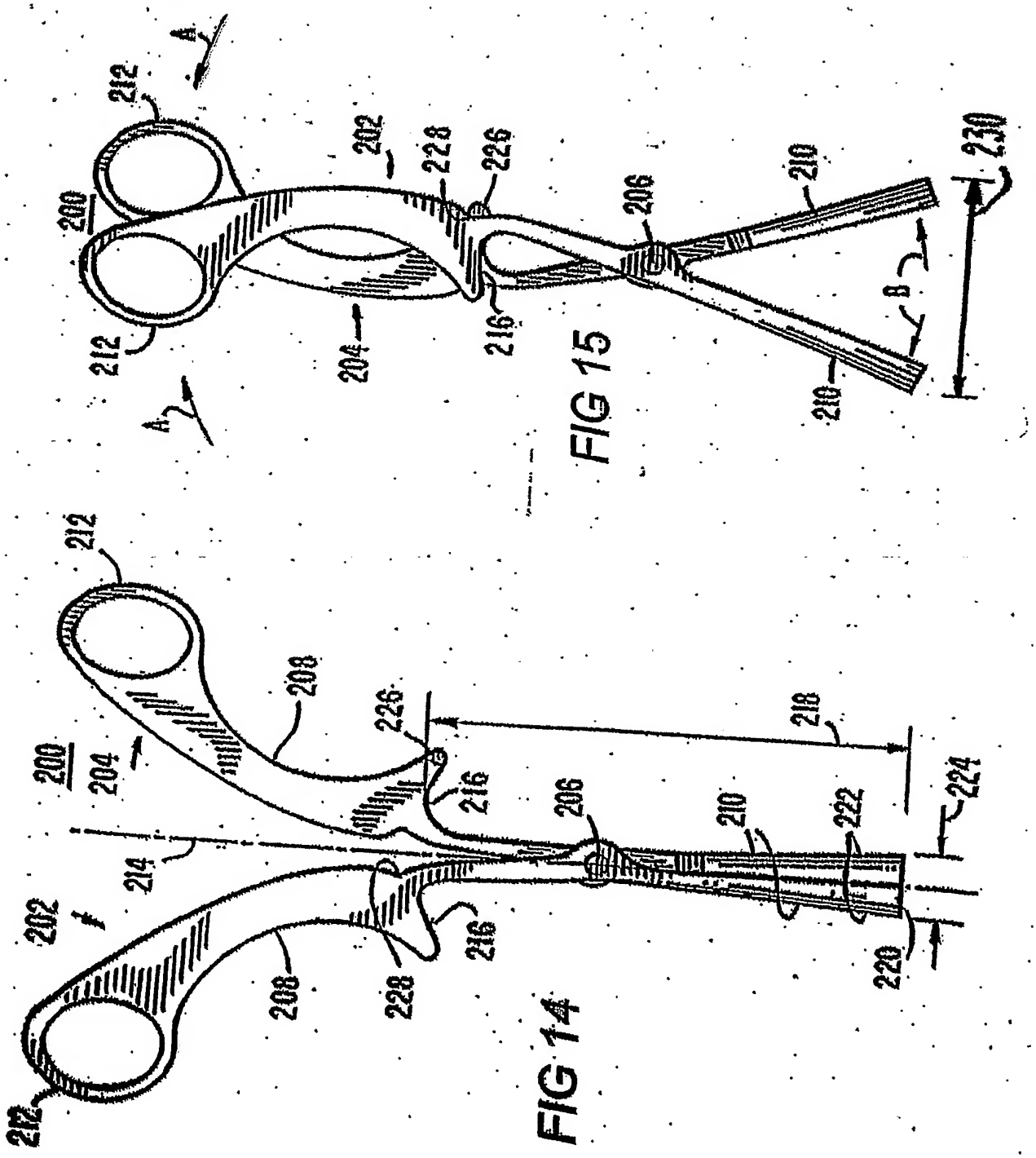

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FIG 15
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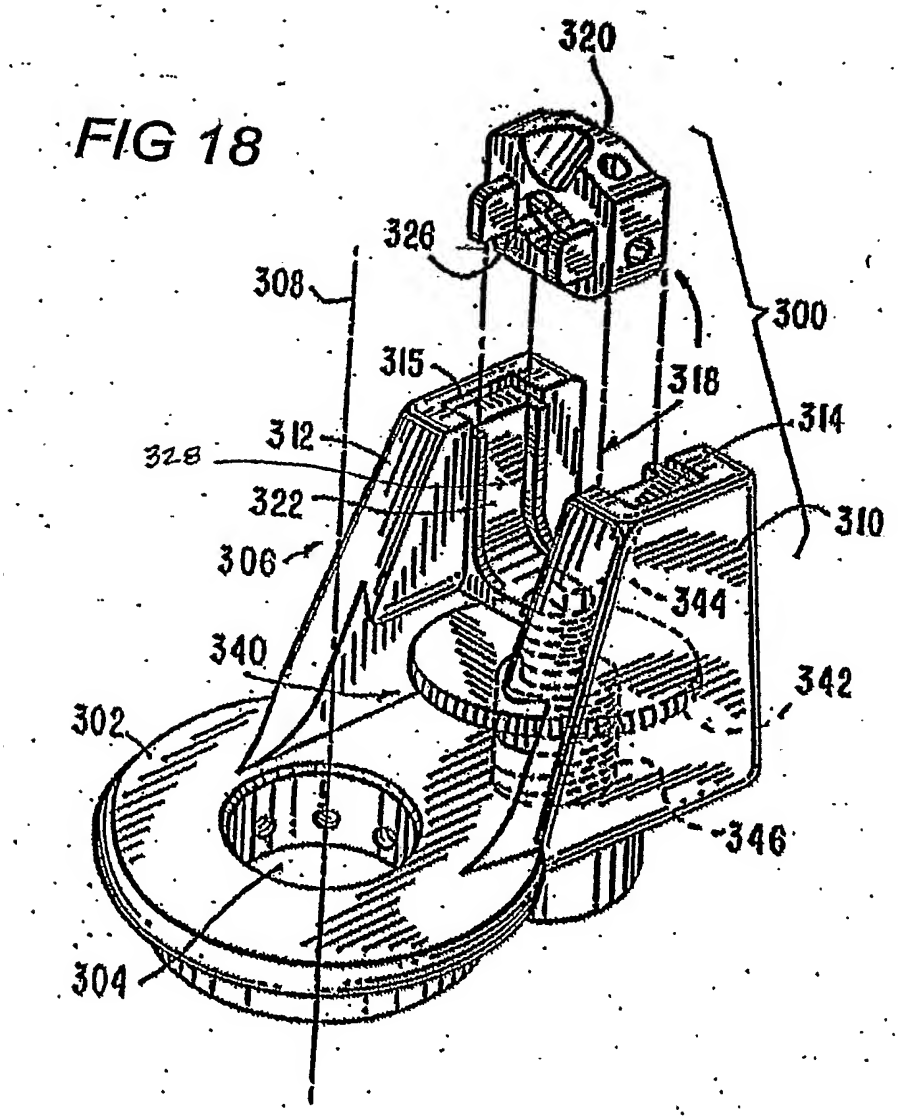
FIG 14

FIG 18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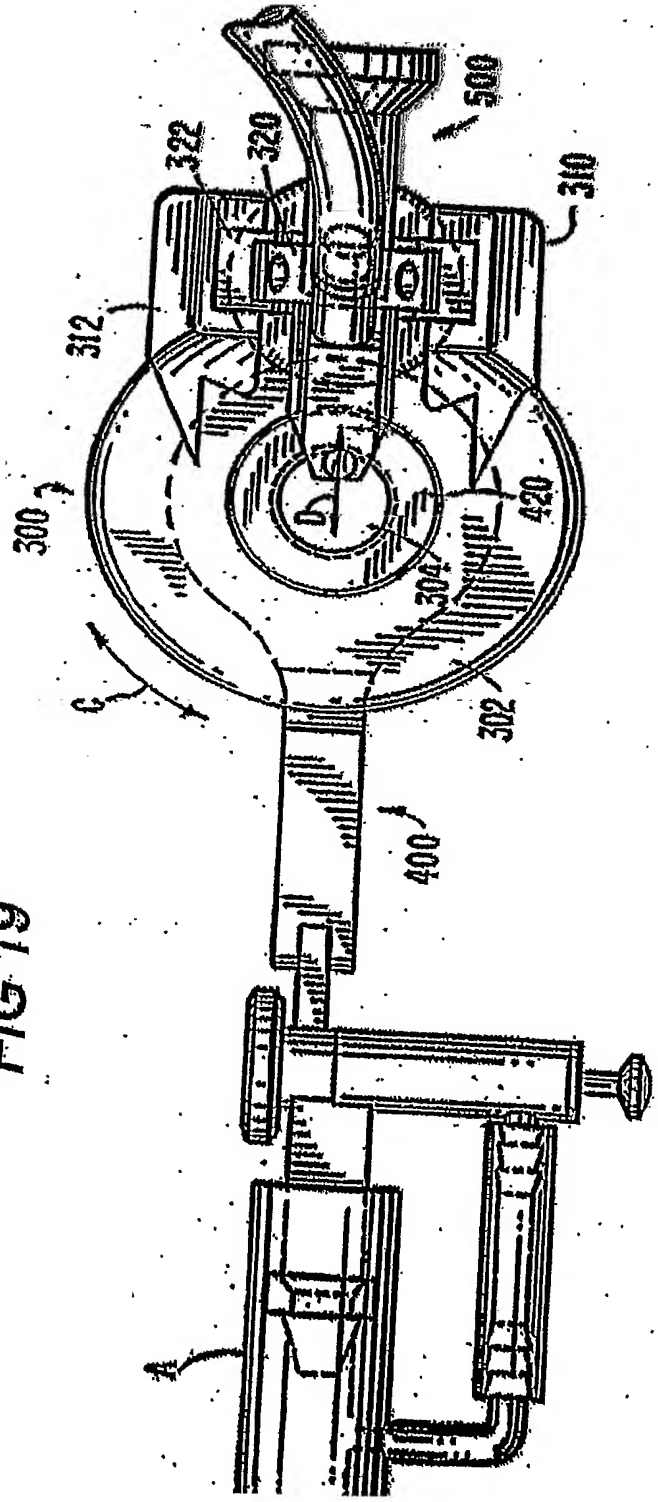

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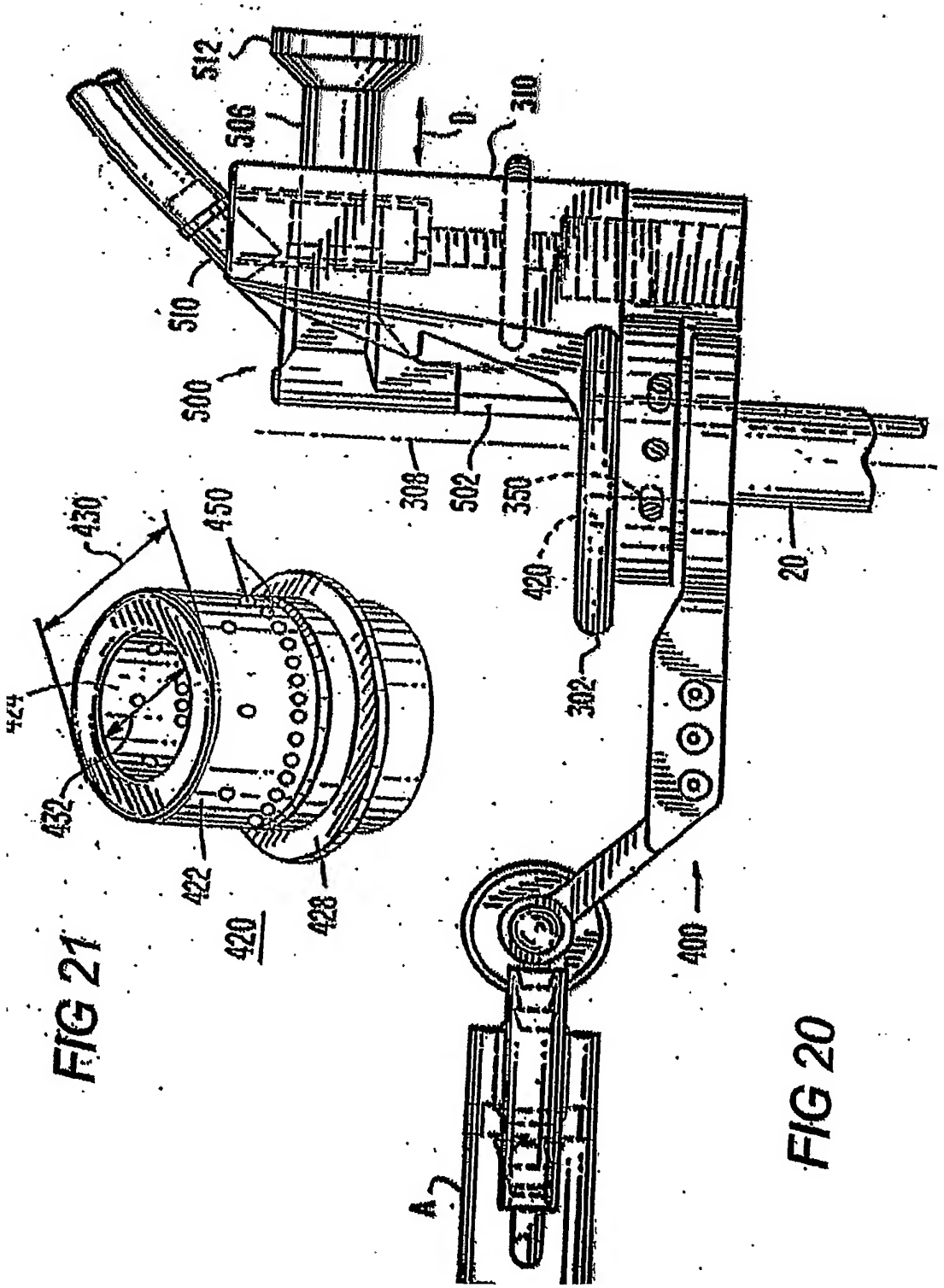
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FIG 21

FIG 20

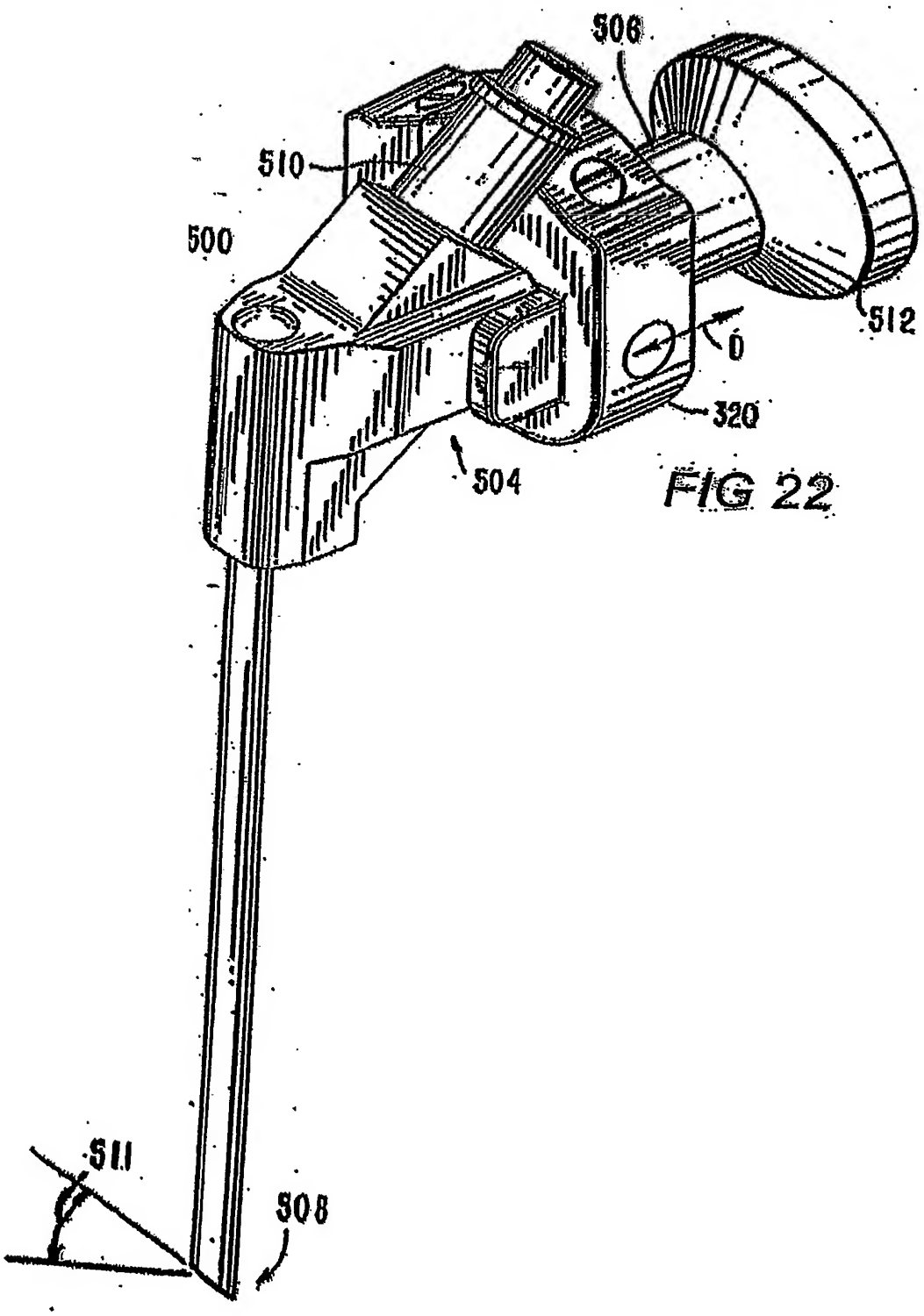


FIG 22

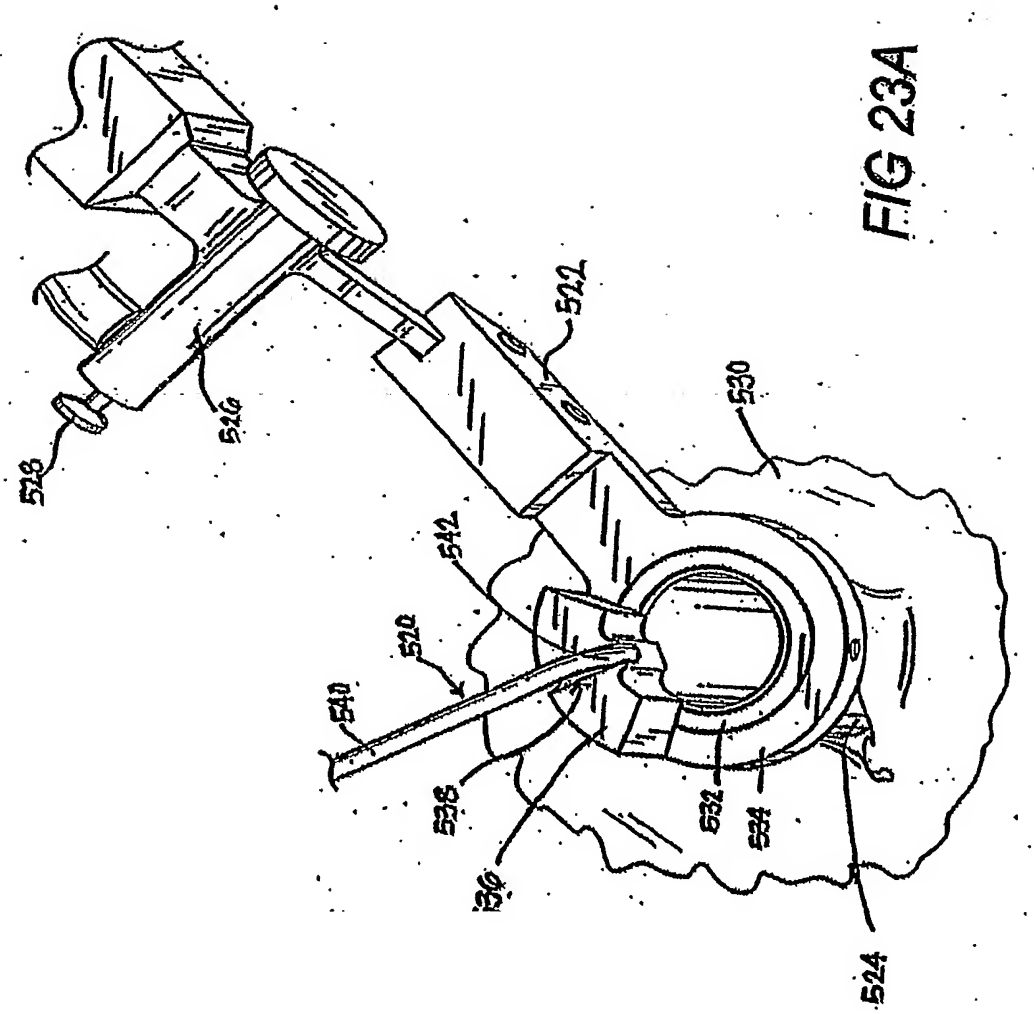
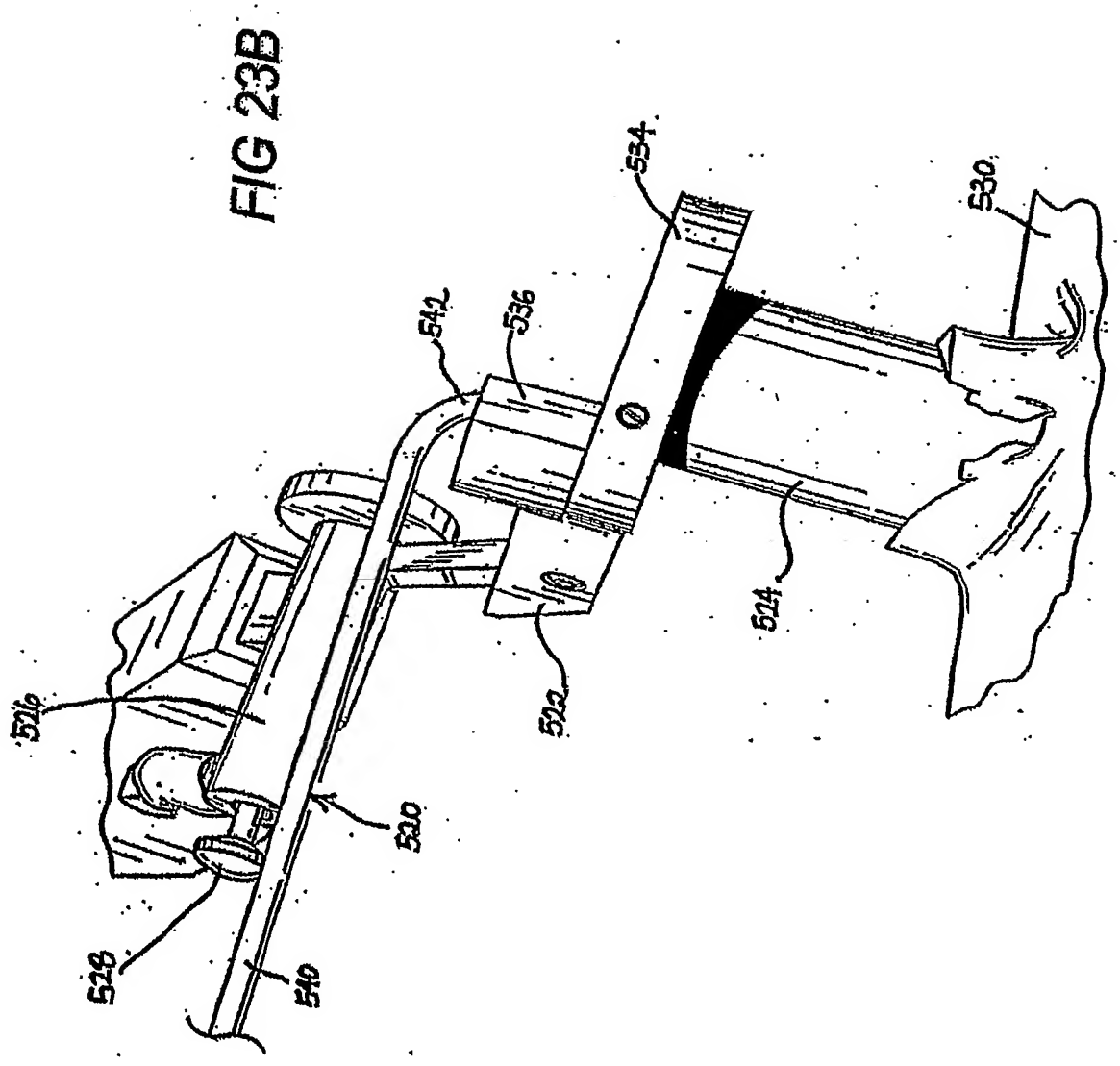


FIG 23A

FIG 23B



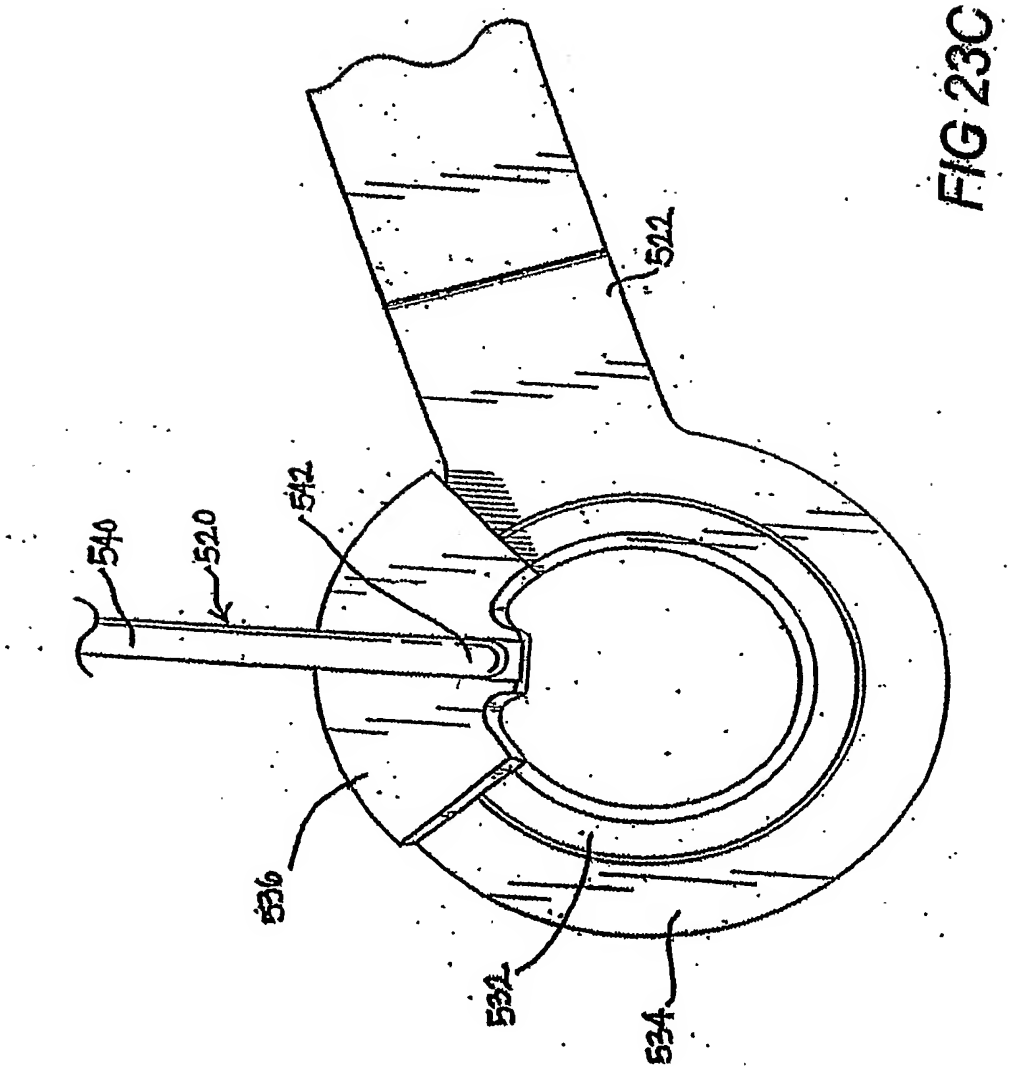


FIG 23C

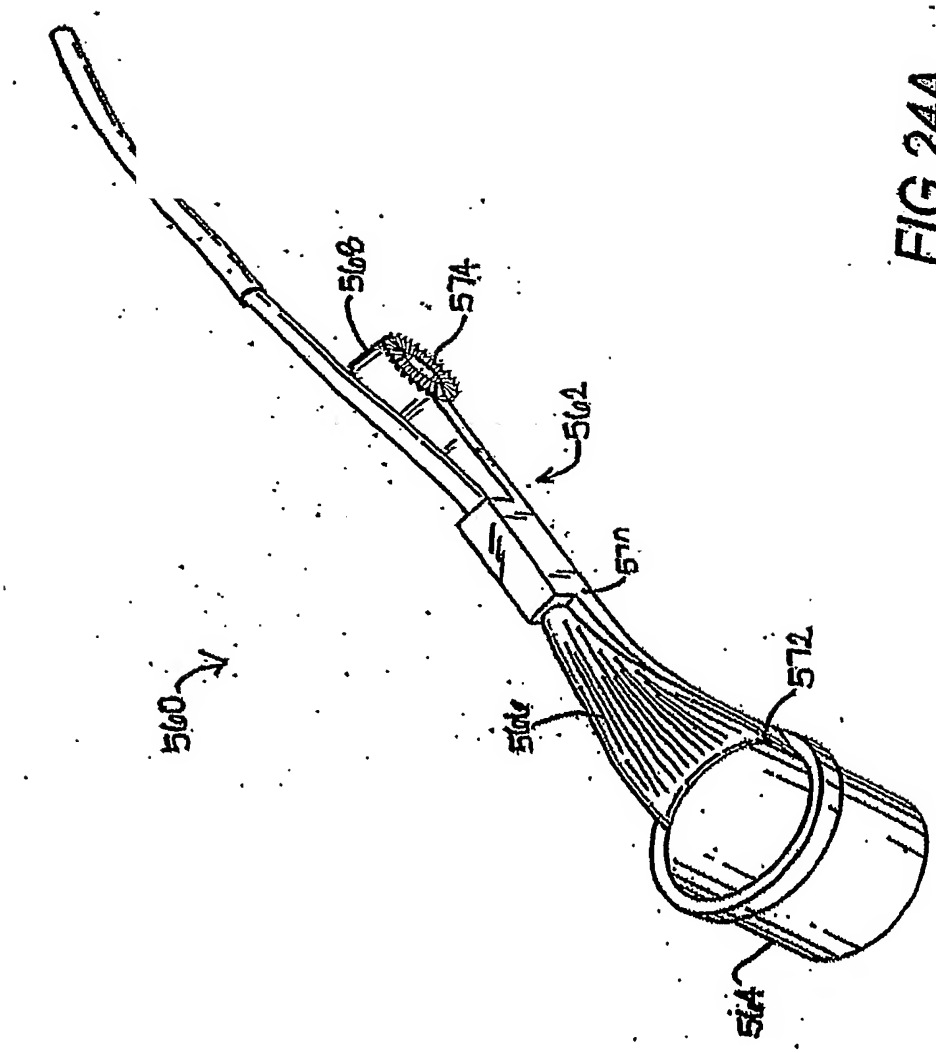


FIG 24A

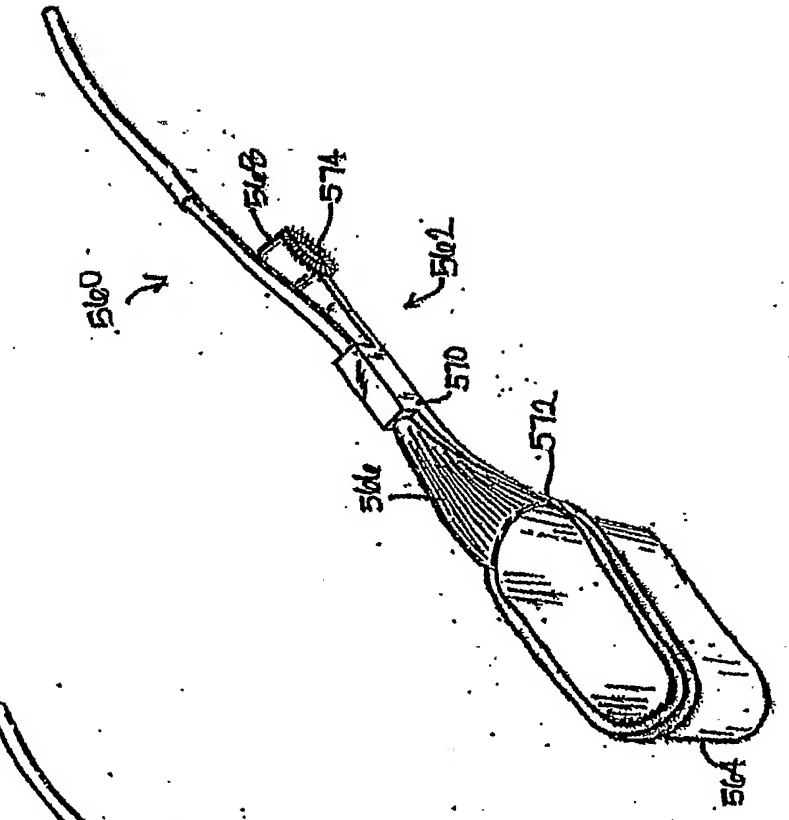


FIG 24C

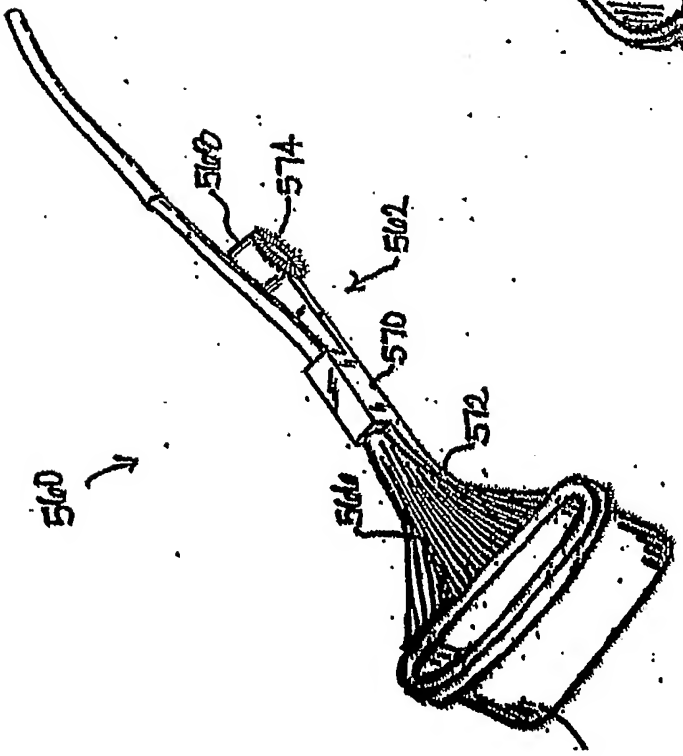


FIG 24B

FIG. 25

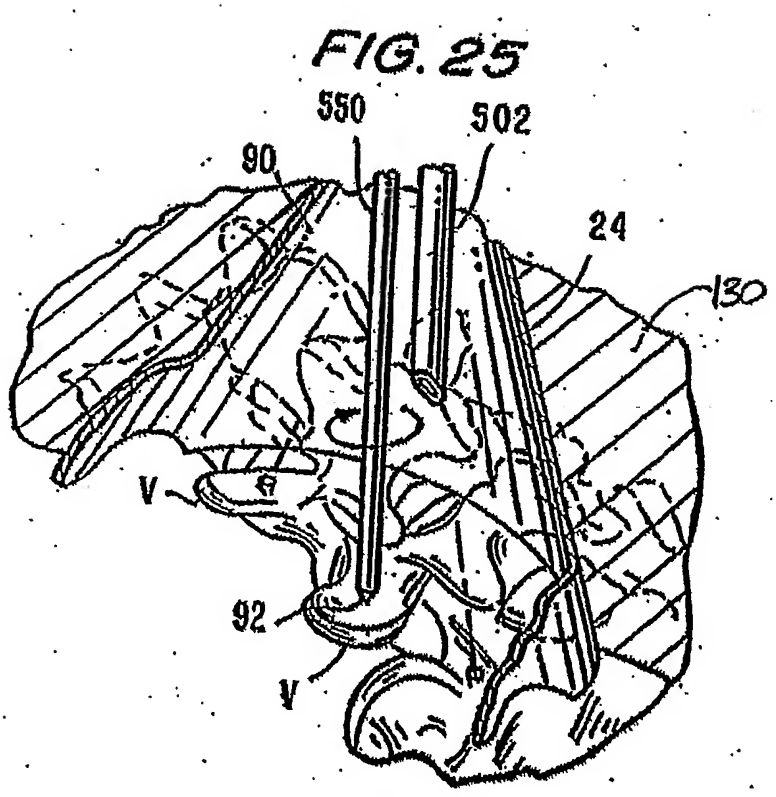
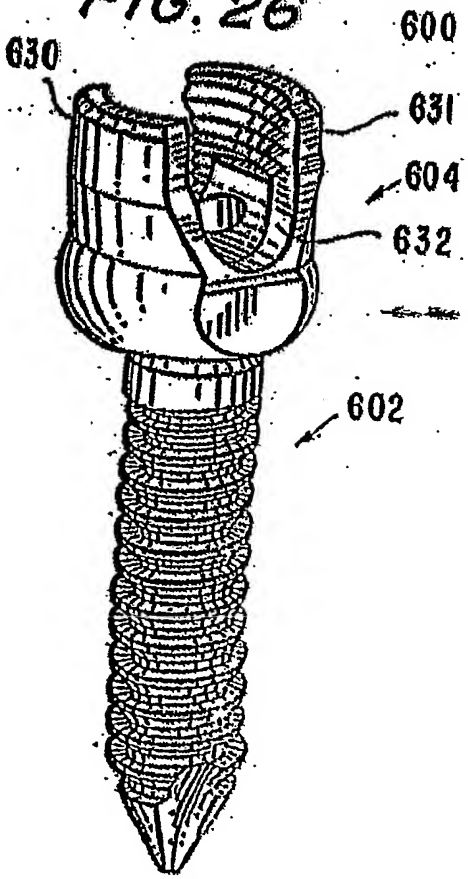


FIG. 26



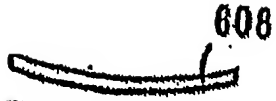


FIG. 27A

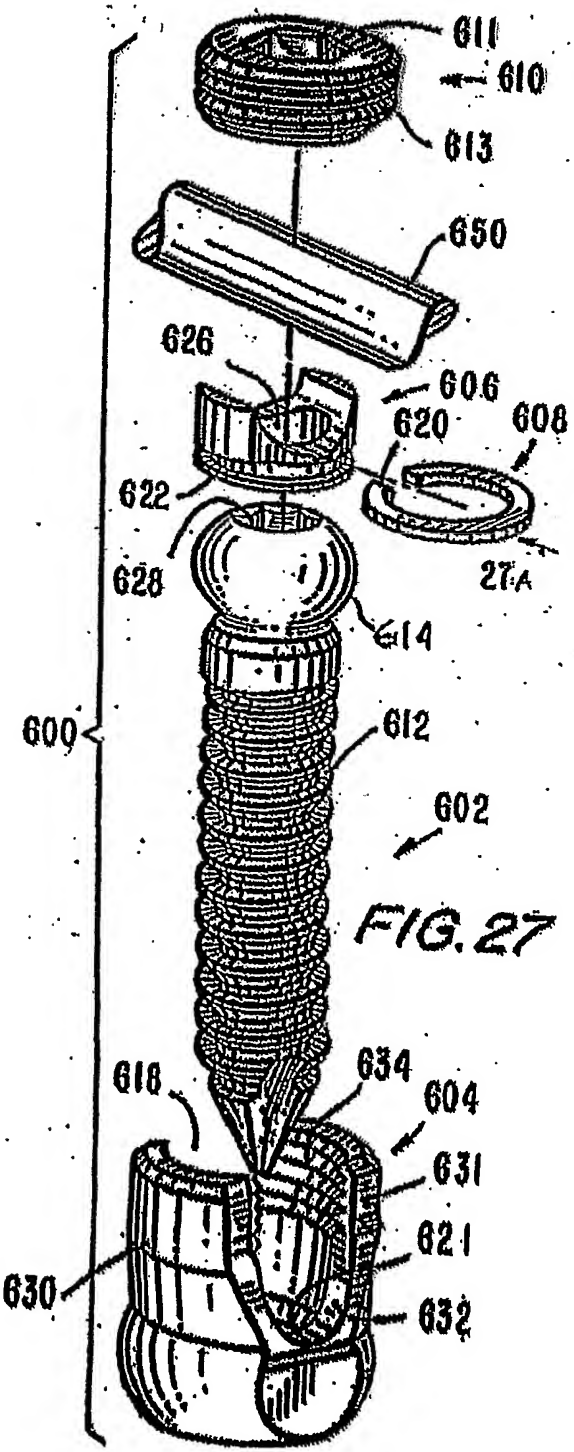


FIG. 27

FIG. 28

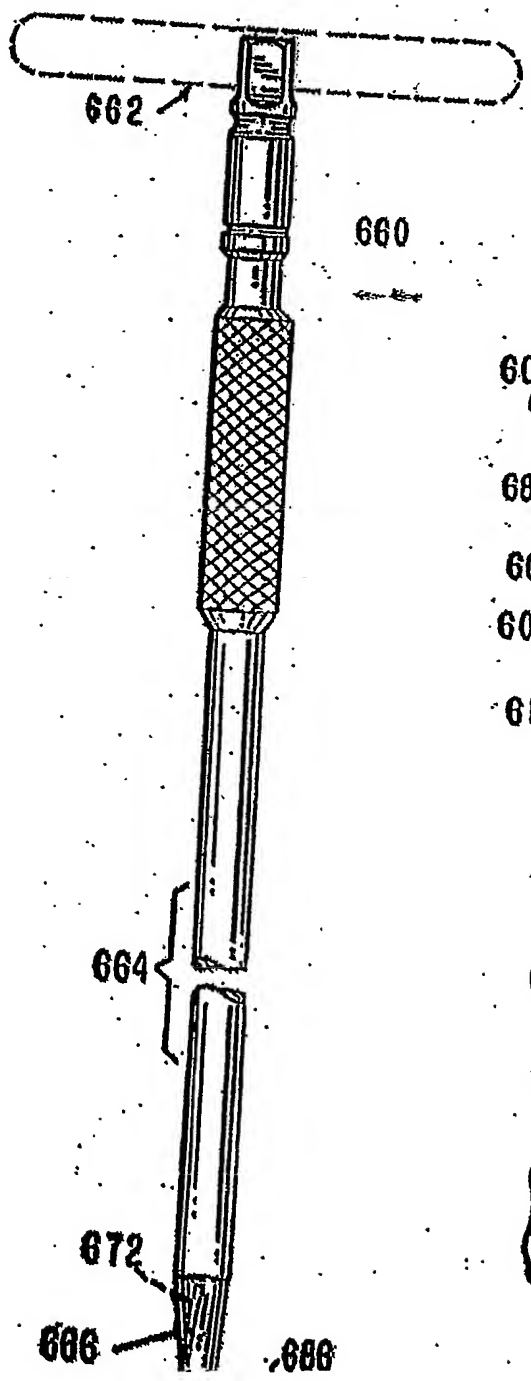

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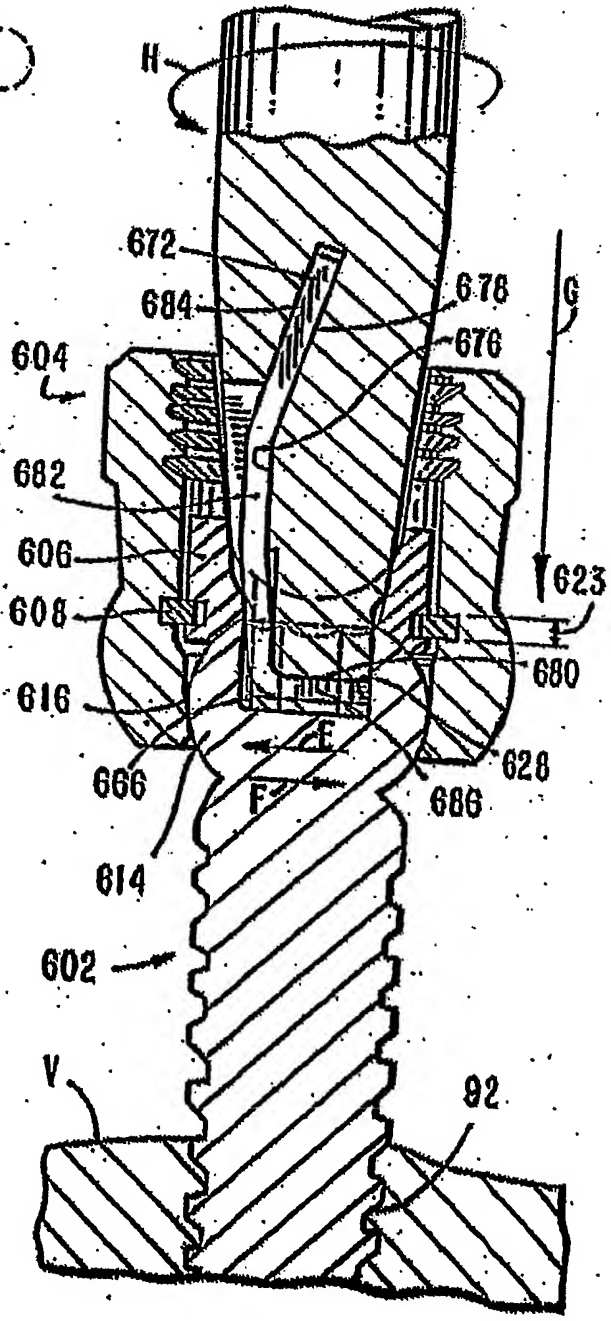
FIG. 29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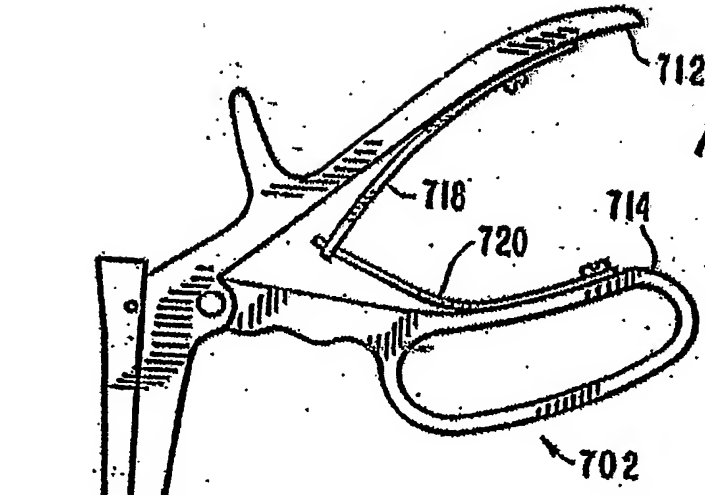
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FIG. 30

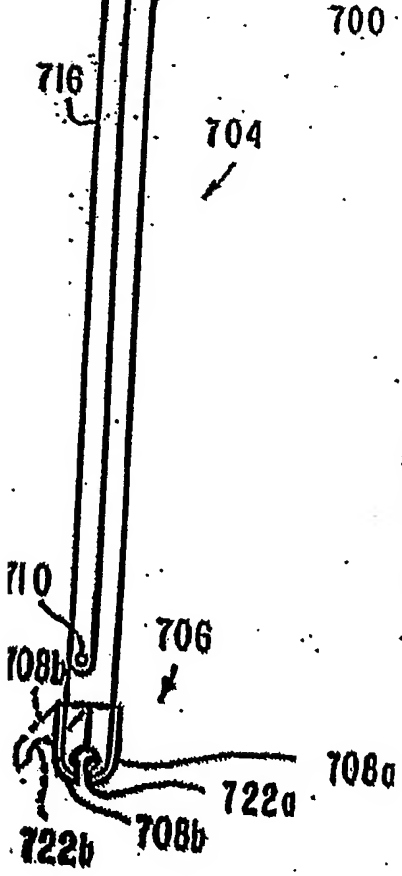
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FIG. 31

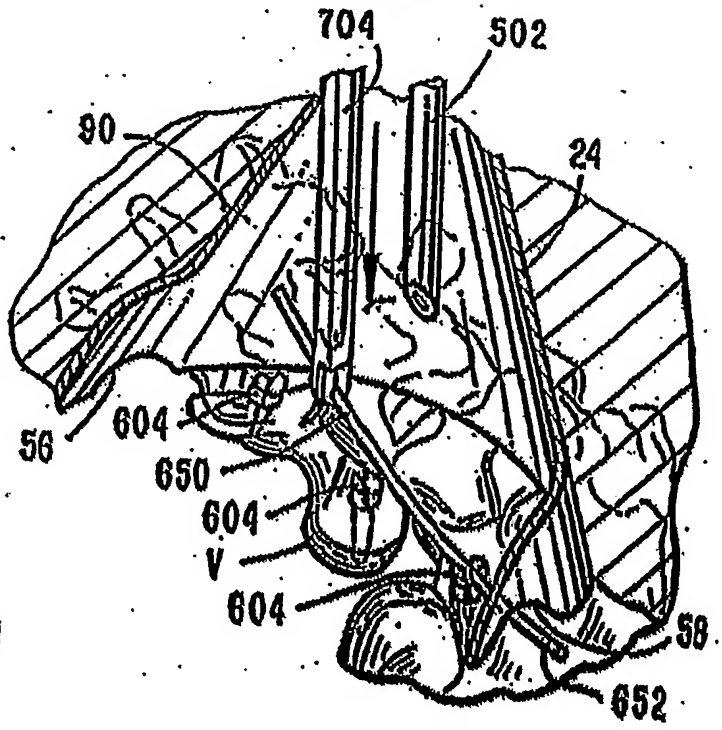
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FIG. 32

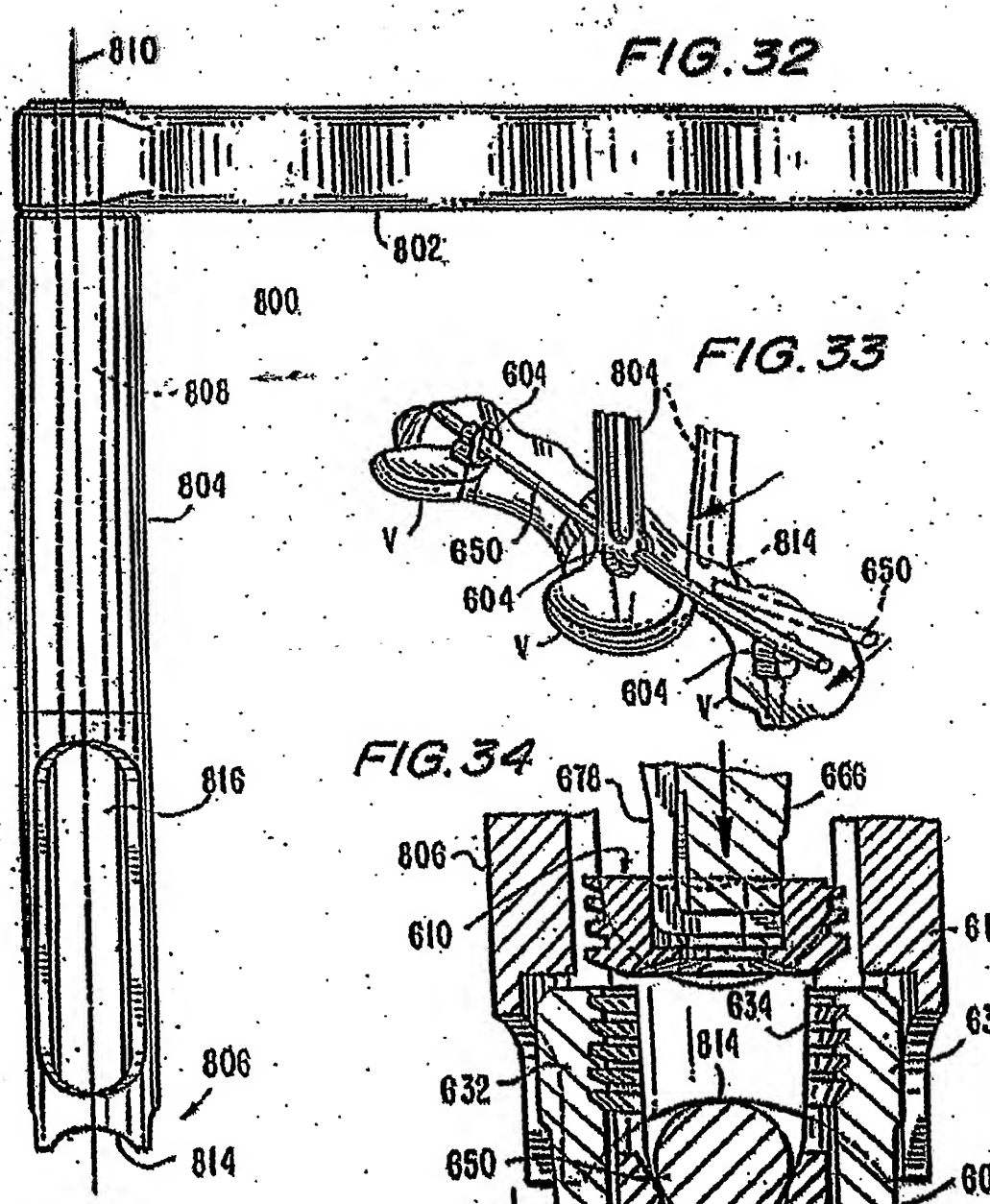

FIG. 33

FIG. 34

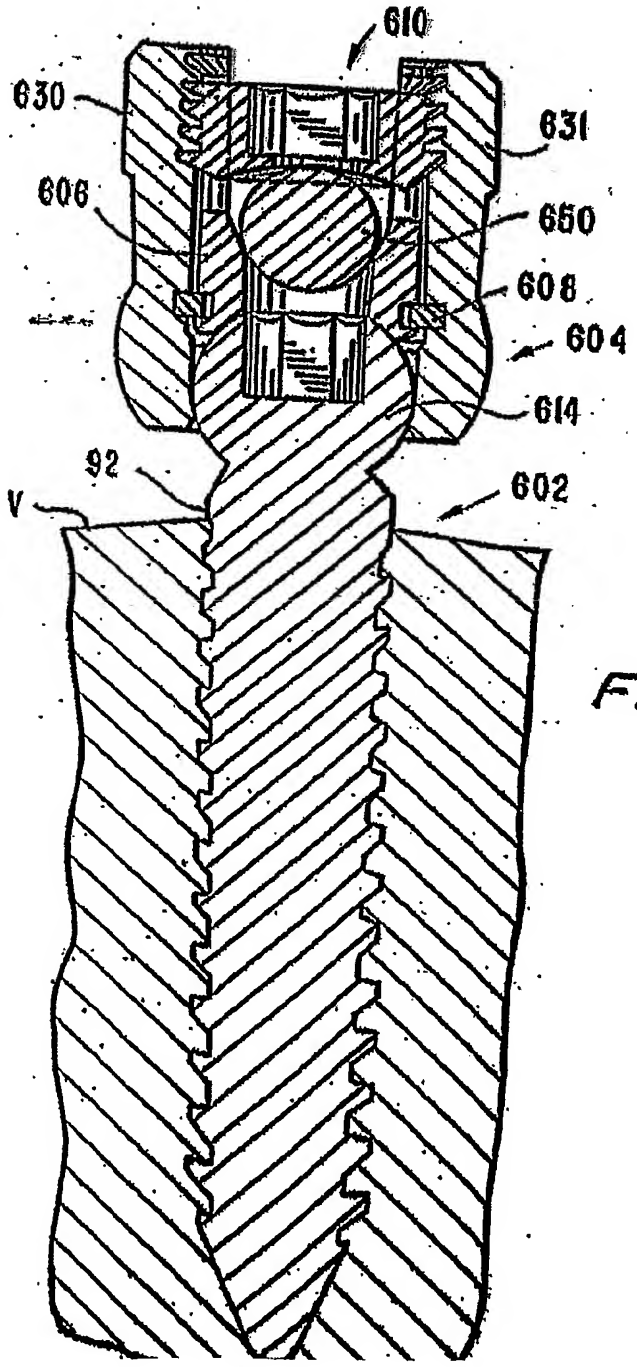

FIG. 35

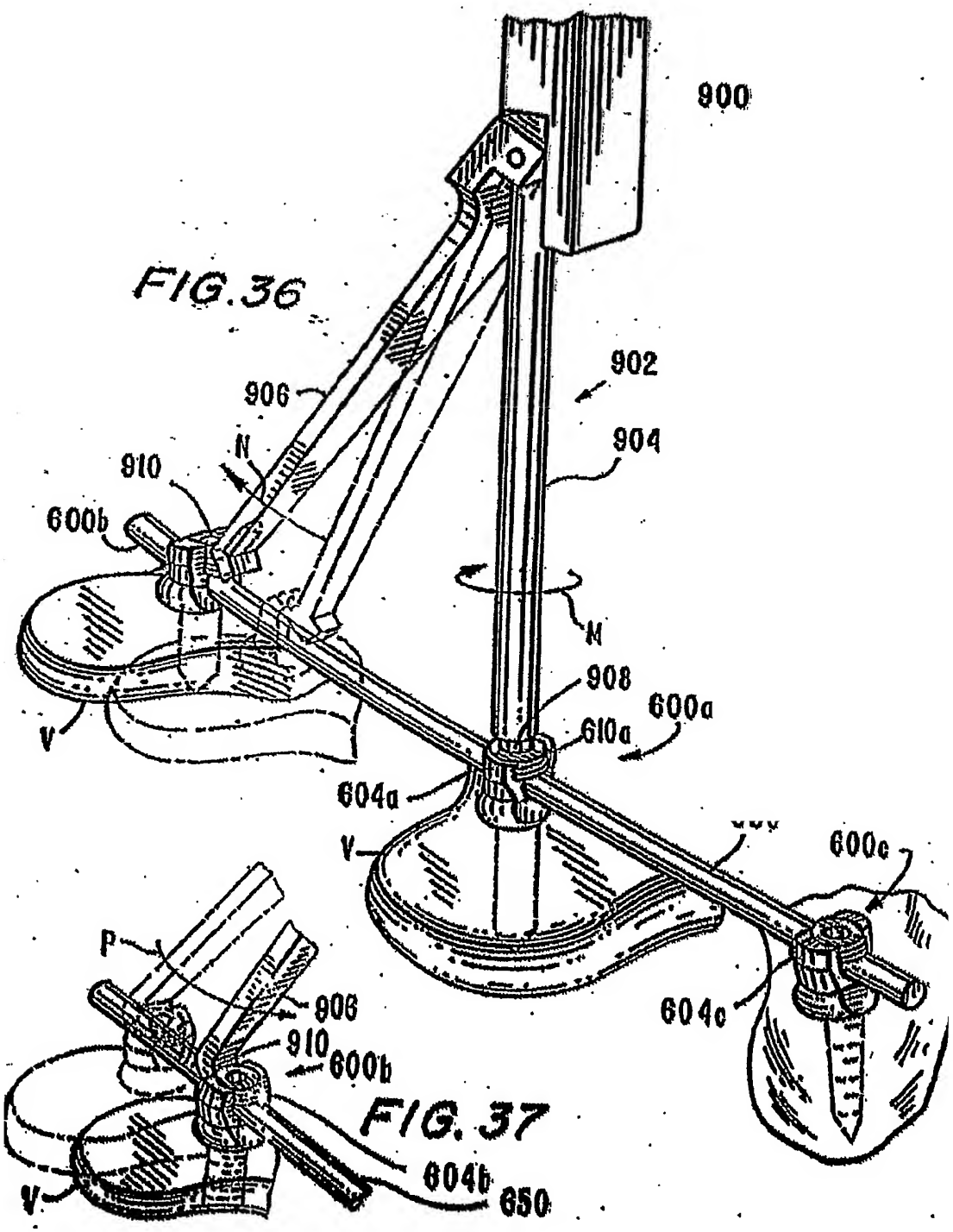
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FIG. 36

FIG. 37

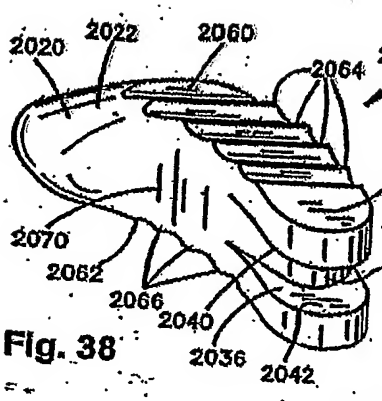


Fig. 38

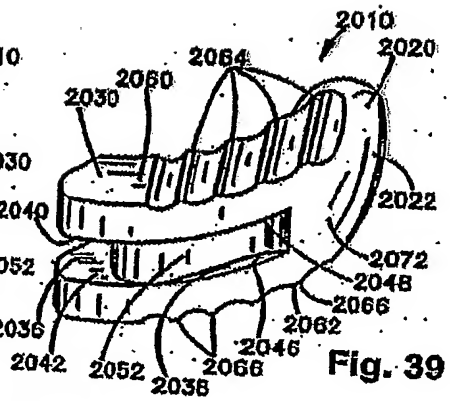


Fig. 39

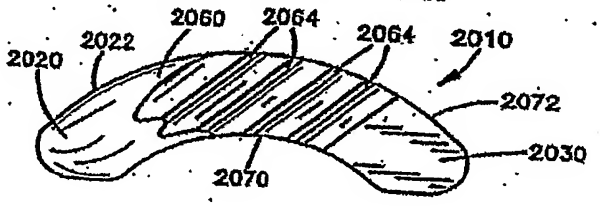


Fig. 40

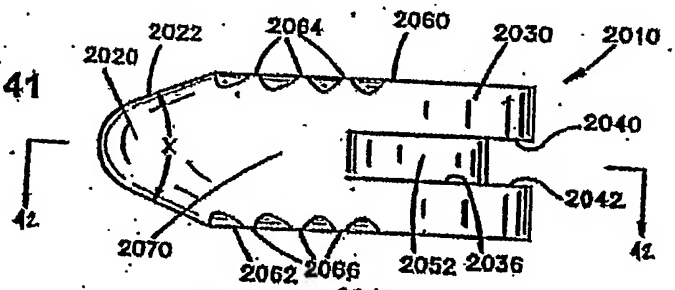


Fig. 41

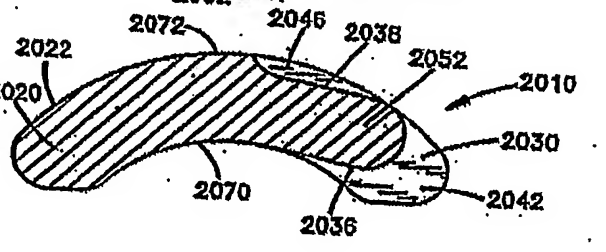


Fig. 42

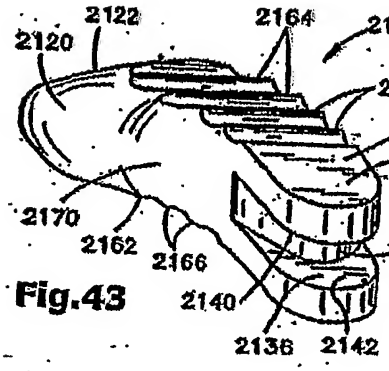


Fig.43

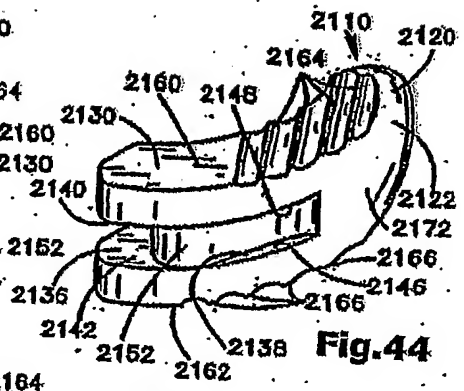


Fig.44

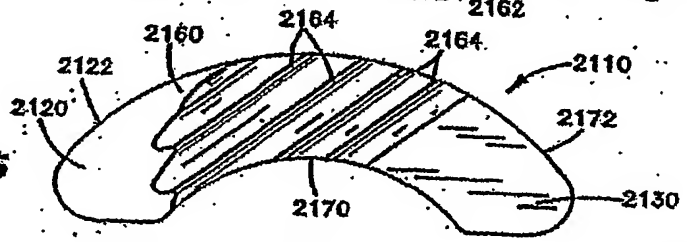


Fig.45

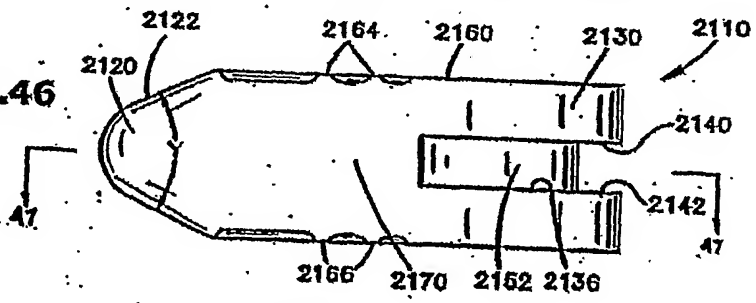


Fig.46

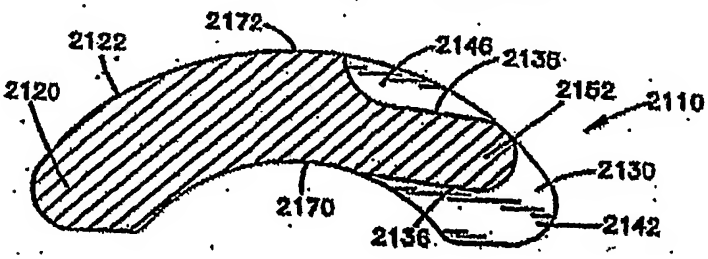


Fig.47

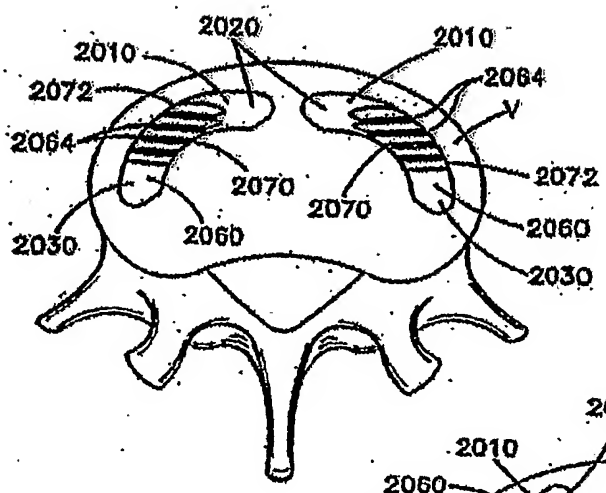


Fig.48

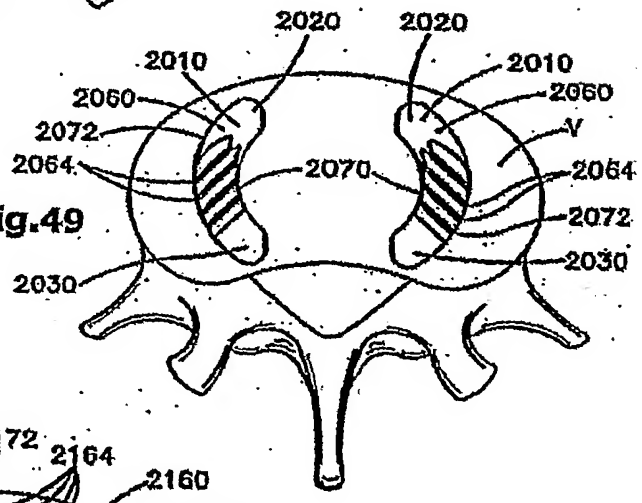


Fig.49

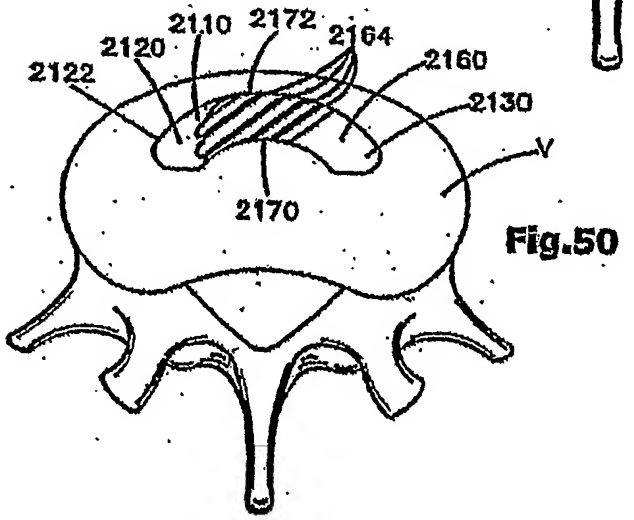


Fig.50

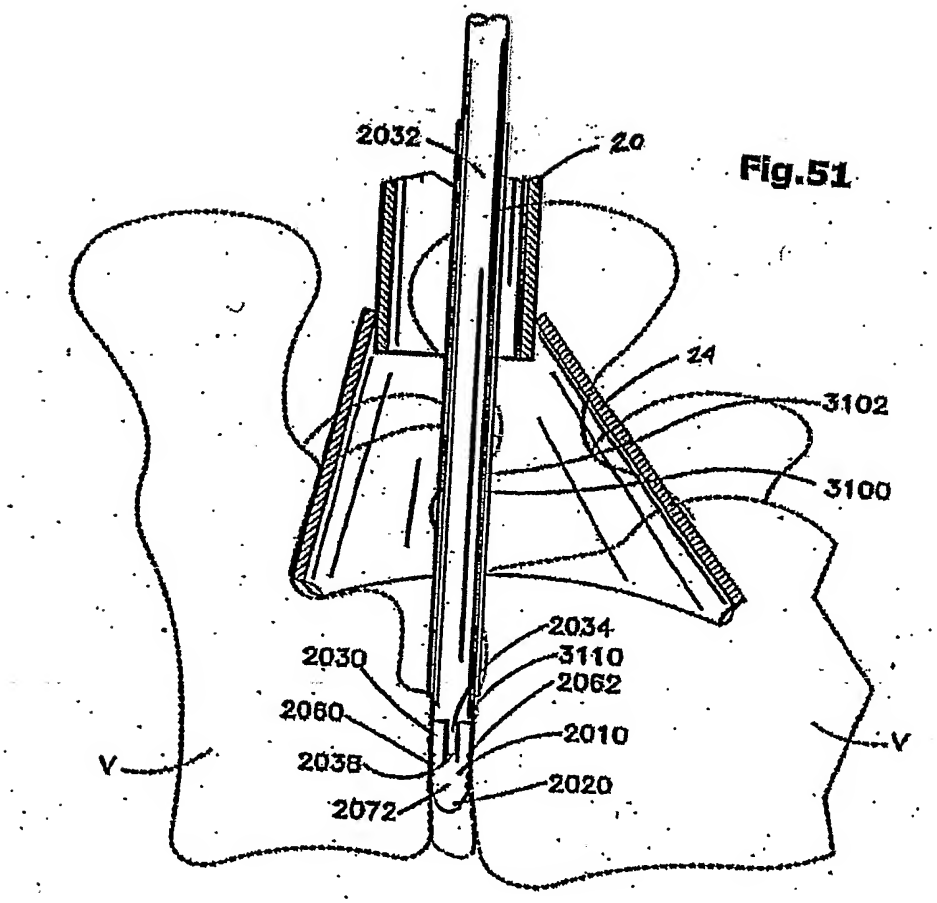

2032
20
24
3102
3100
2034
3110
2062
2030
2060
2010
2038
2020
2072
V
V

Fig.51

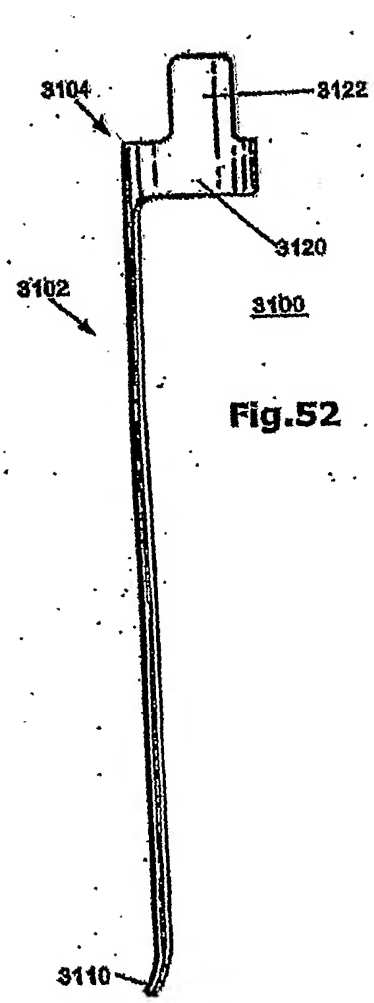


Fig.52

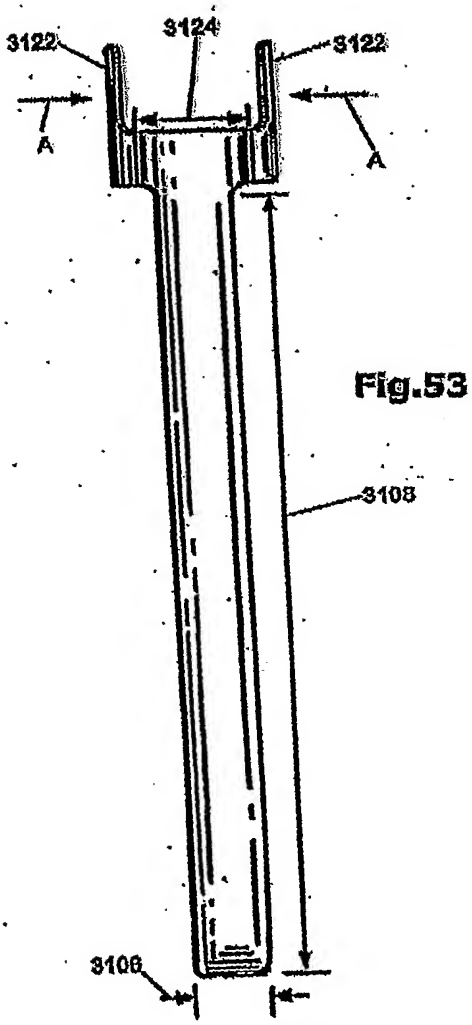
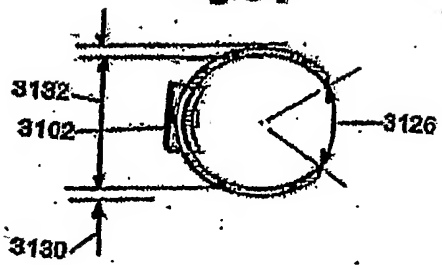


Fig.53

Fig.54



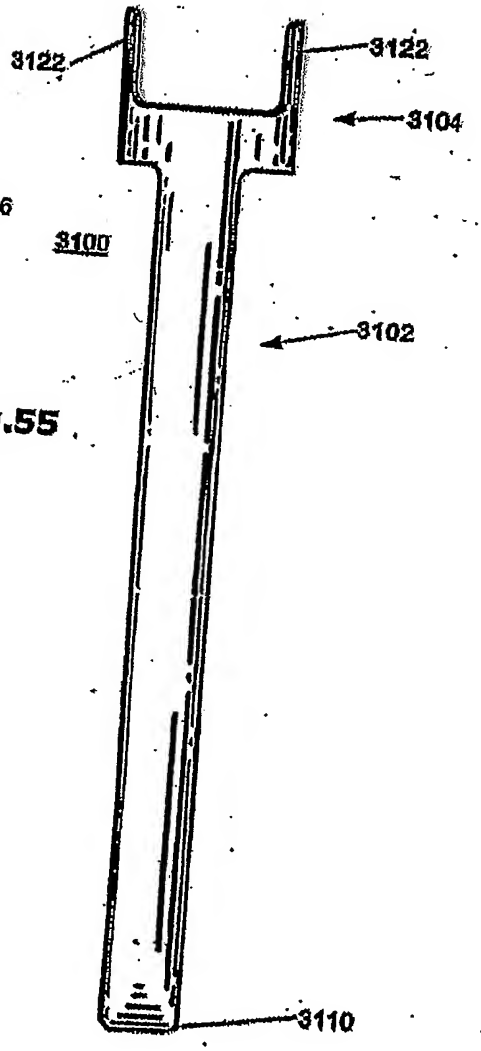


Fig.55

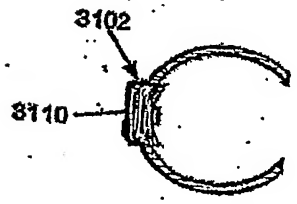


Fig.56

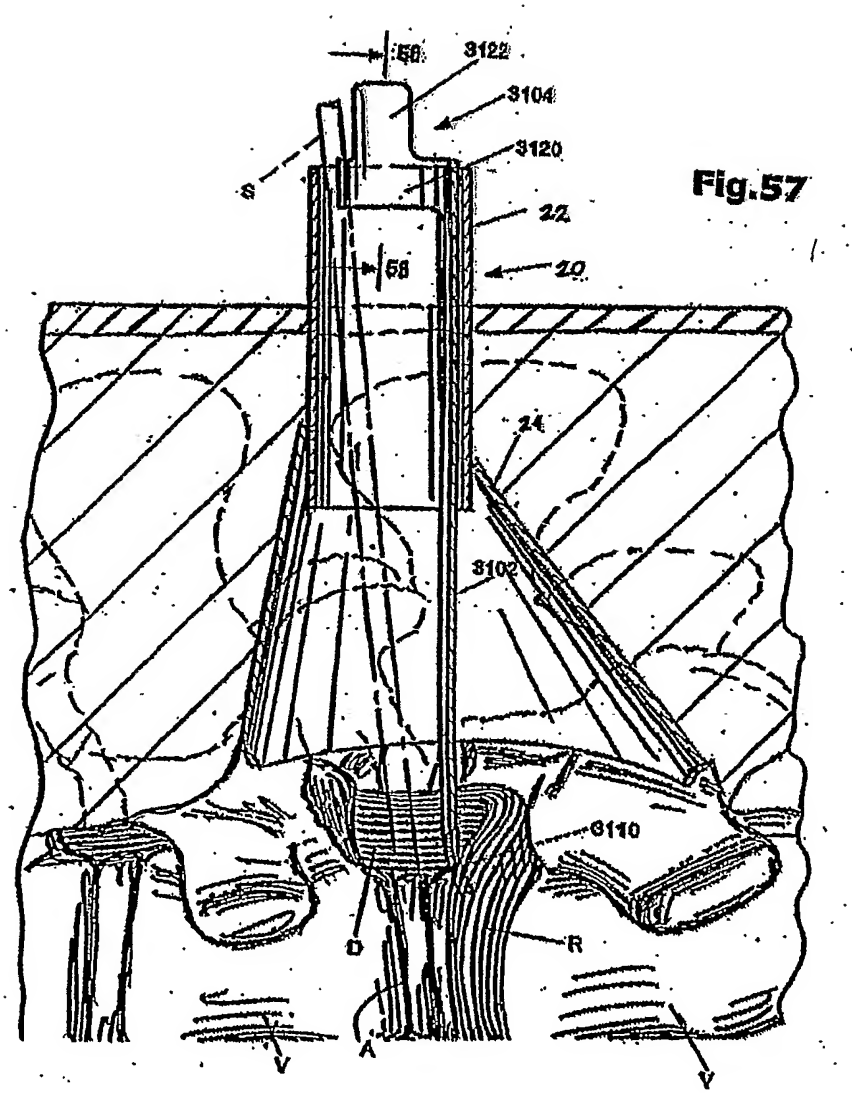


Fig.57

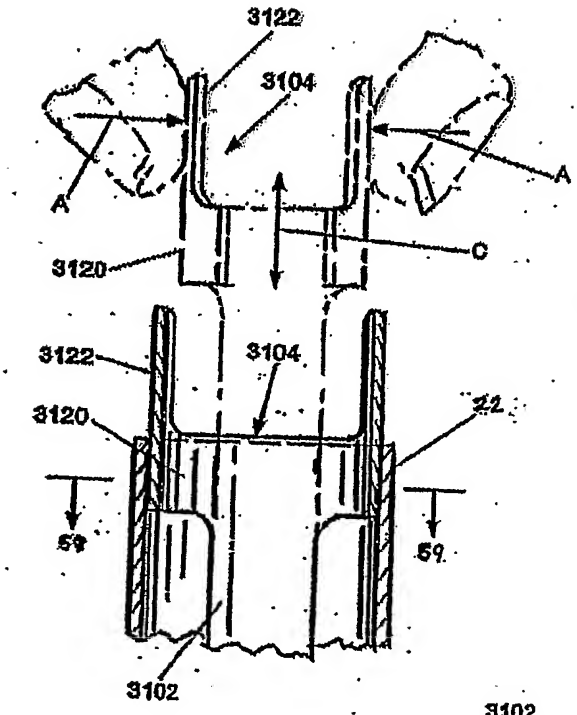

3122
3104
A
A
C
3120
3122
3104
3120
22
59
59
3102

Fig.58

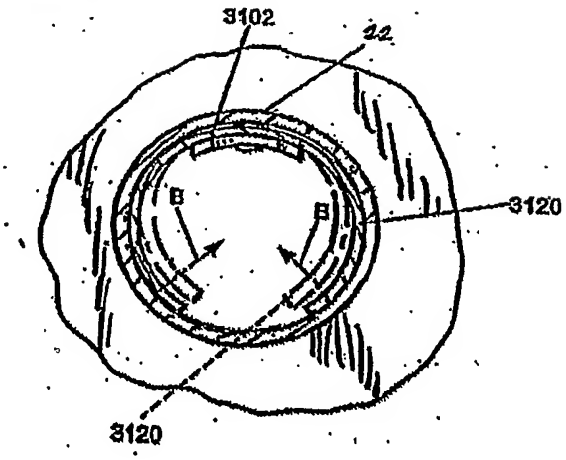

3102
22
B
B
3120
3120

Fig.59

Fig.60

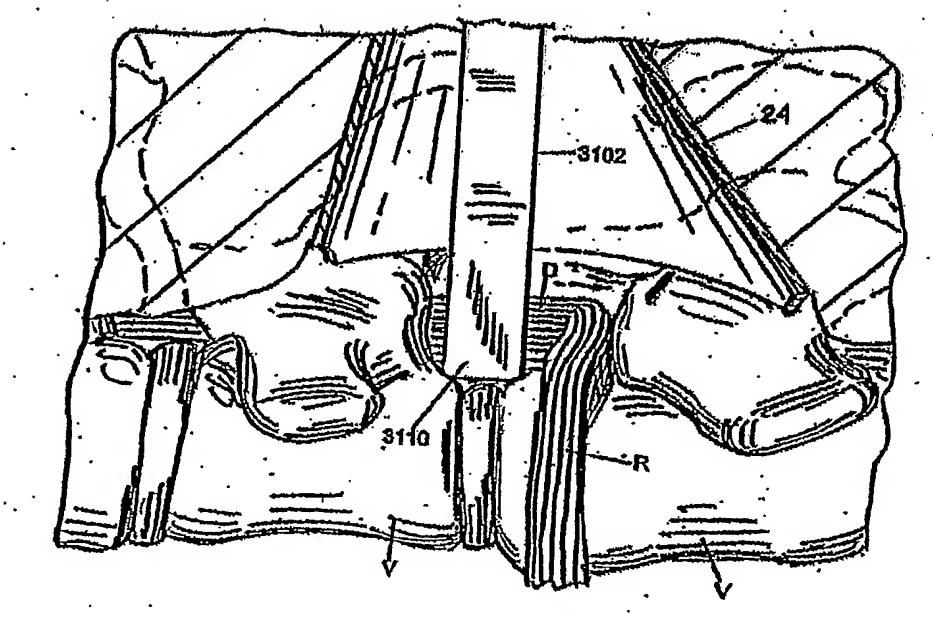


Fig.61

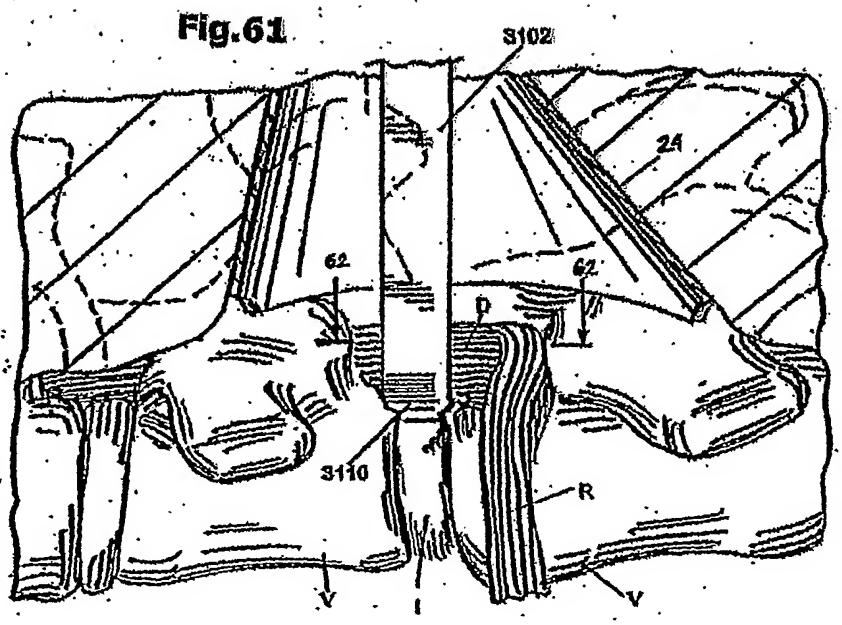
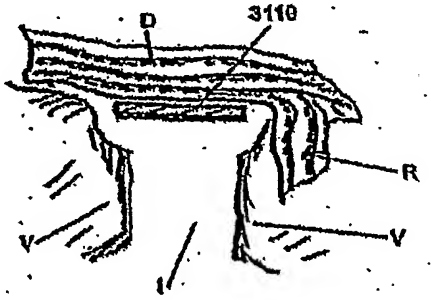


Fig.62



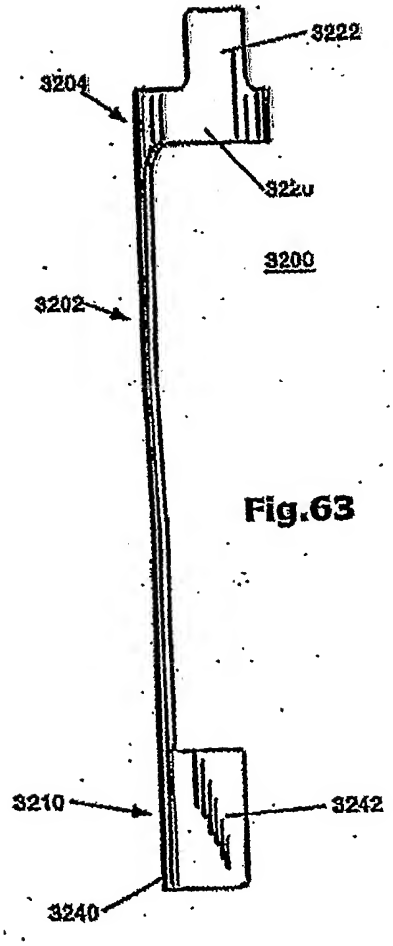

3222
3204
3220
3200
3202
3210
3242
3240

Fig.63

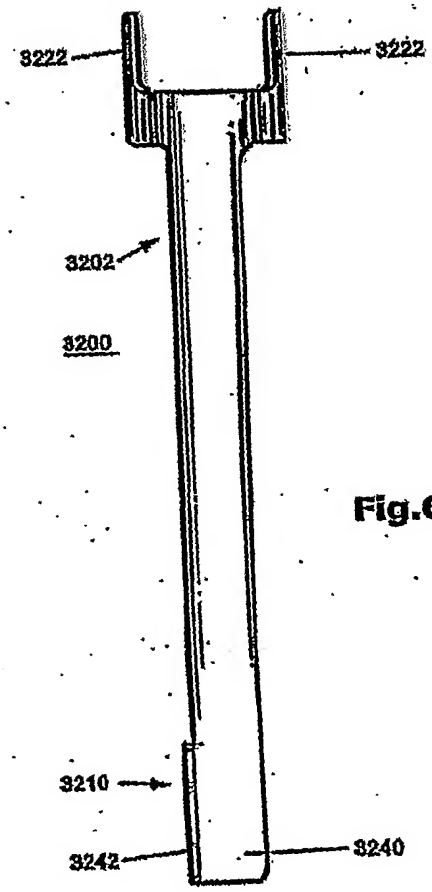
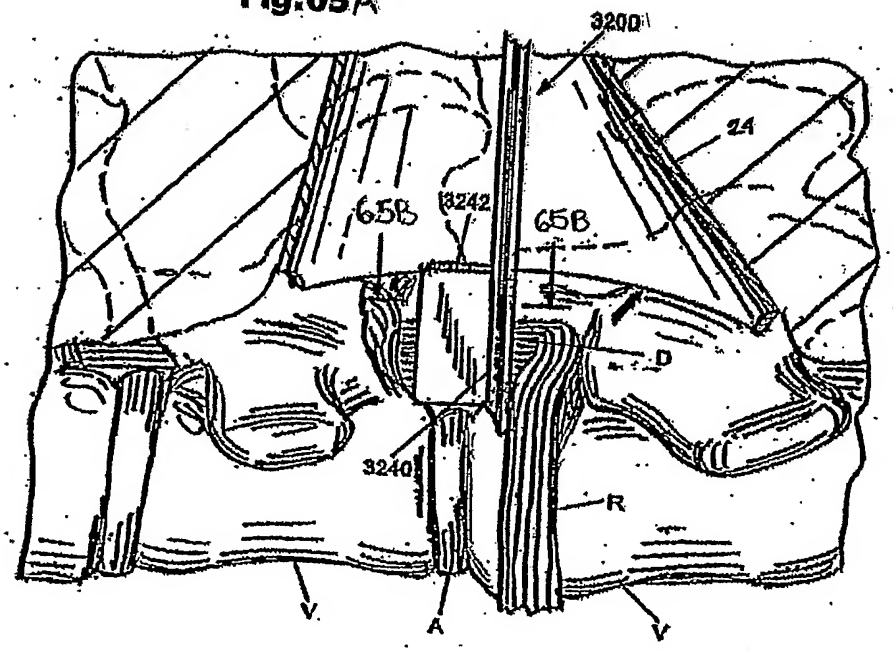

3222
3222
3202
3200
3210
3242
3240

Fig.64

Fig.65A



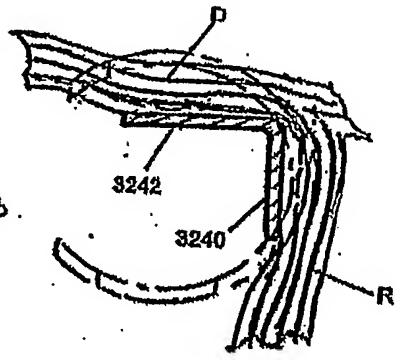


Fig.65B

FIG. 66A

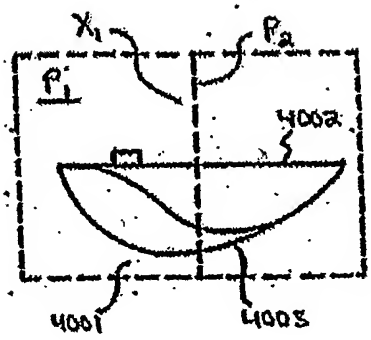


FIG. 66B

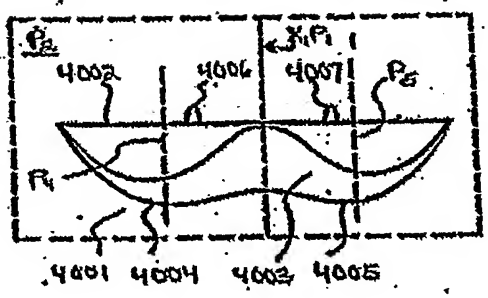


FIG. 66C

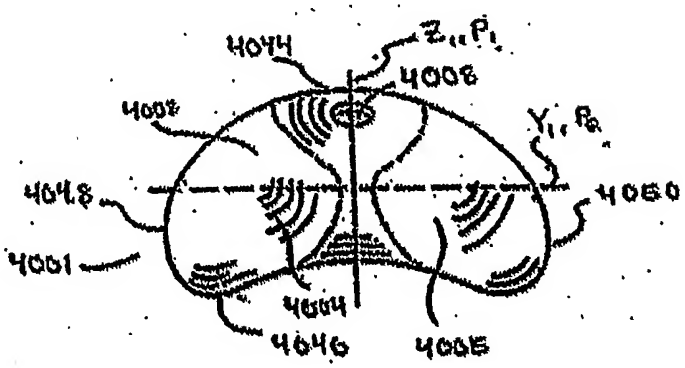


FIG. 67A

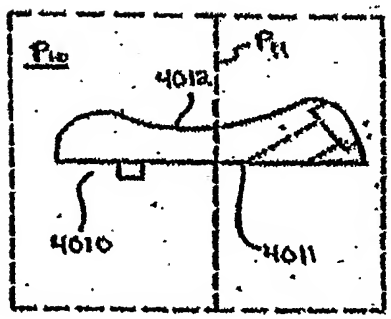


FIG. 67B

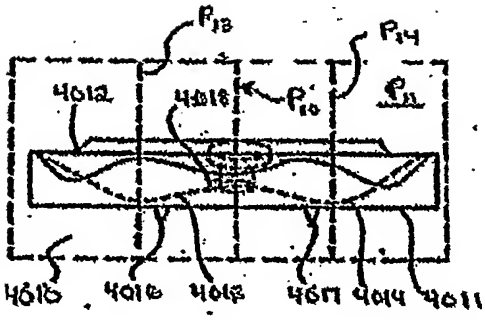


FIG. 67C

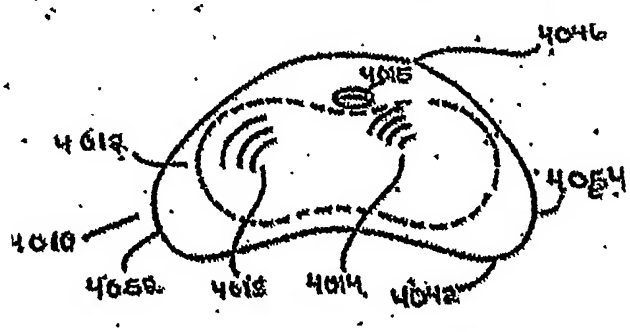


FIG. 68A

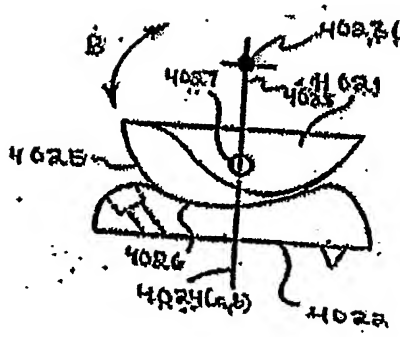


FIG. 68B

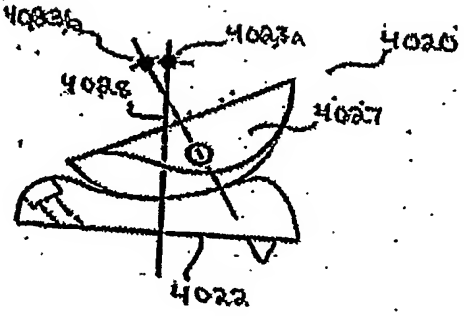


FIG. 69A

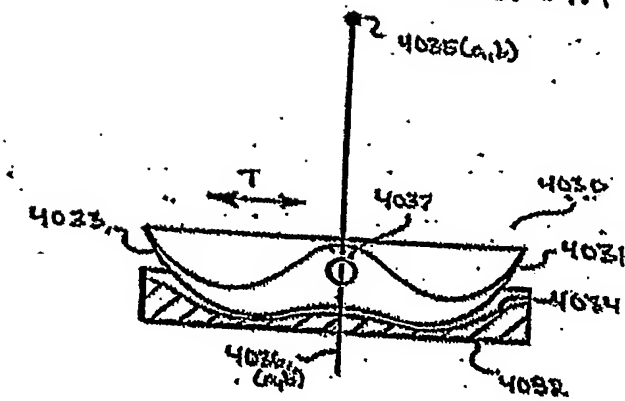


FIG. 69B

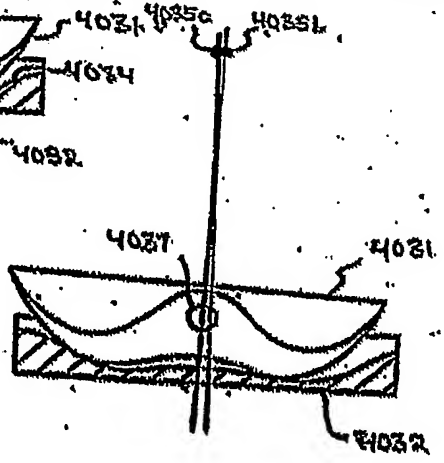


FIG. 70A

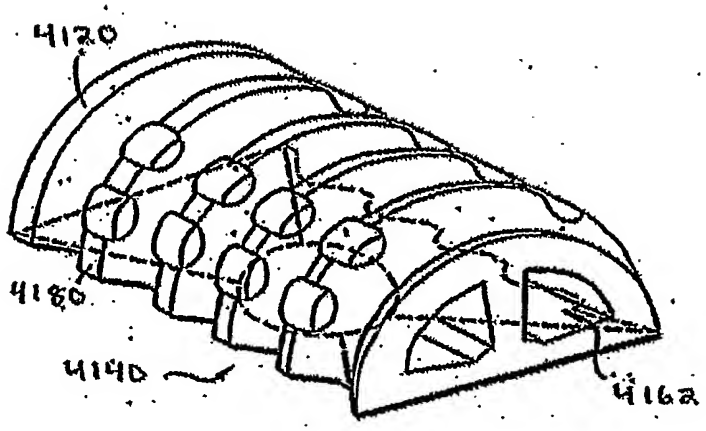


FIG. 70B

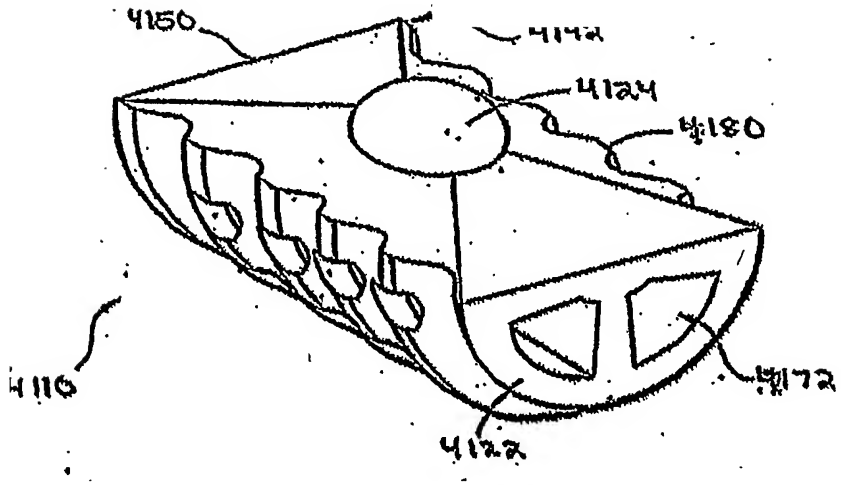
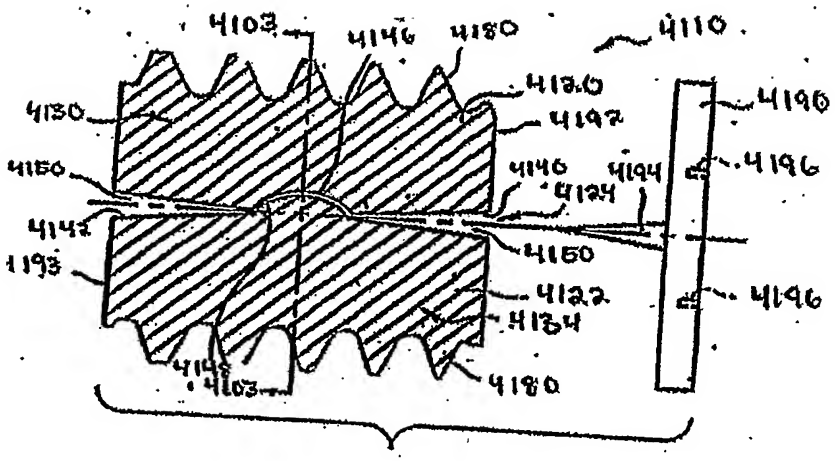


FIG. 71


4103
4146
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4110
4130
4196
4192
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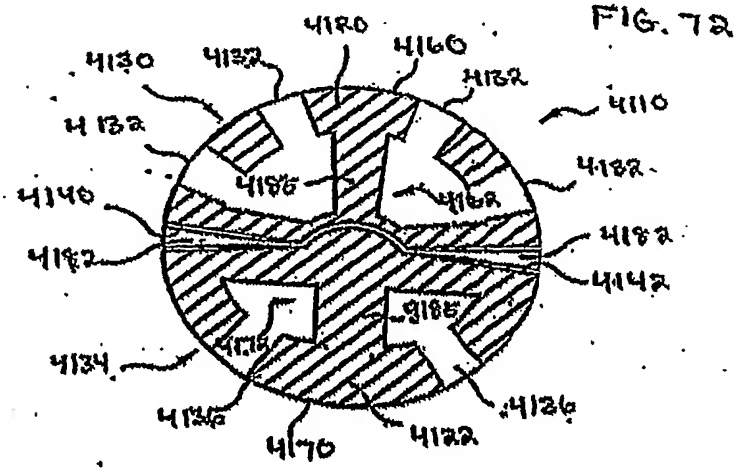
4140
4194
4196
4124
4142
4160
4193
4122
4196
4134
4145
4103
4180

FIG. 72


4120
4160
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4132
4182
4110
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4182
4140
4162
4182
4142
4188
4134
4136
4170
4122
4136

FIG. 73

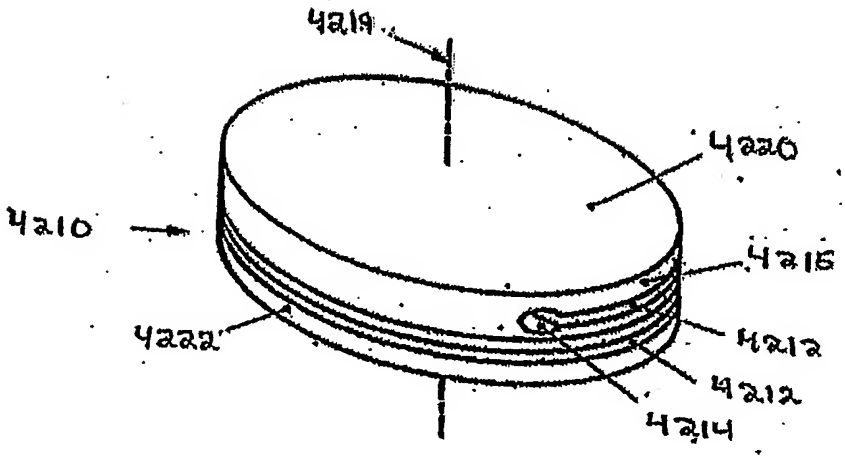


FIG. 74

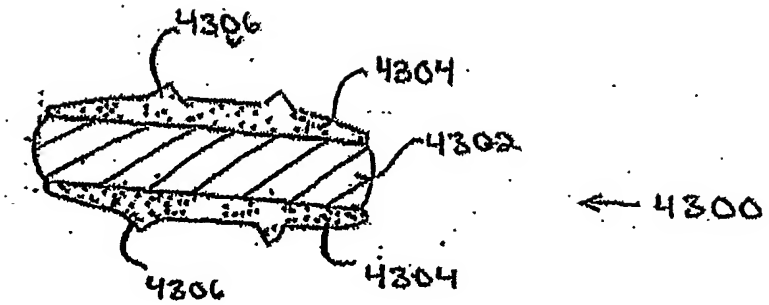


FIG. 75

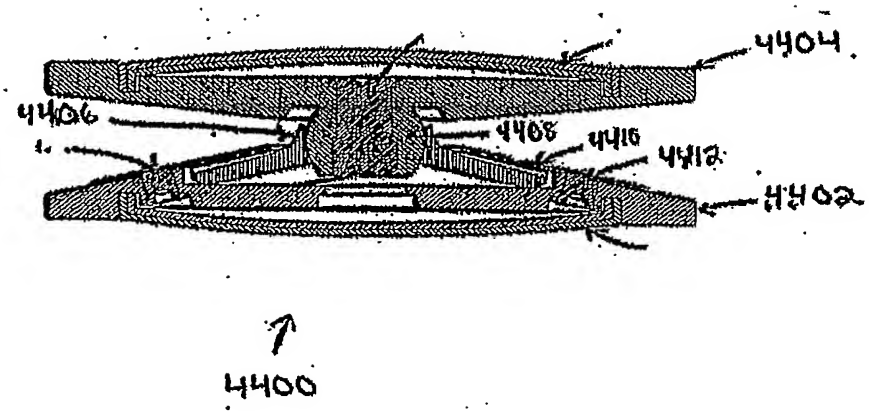


FIG. 76

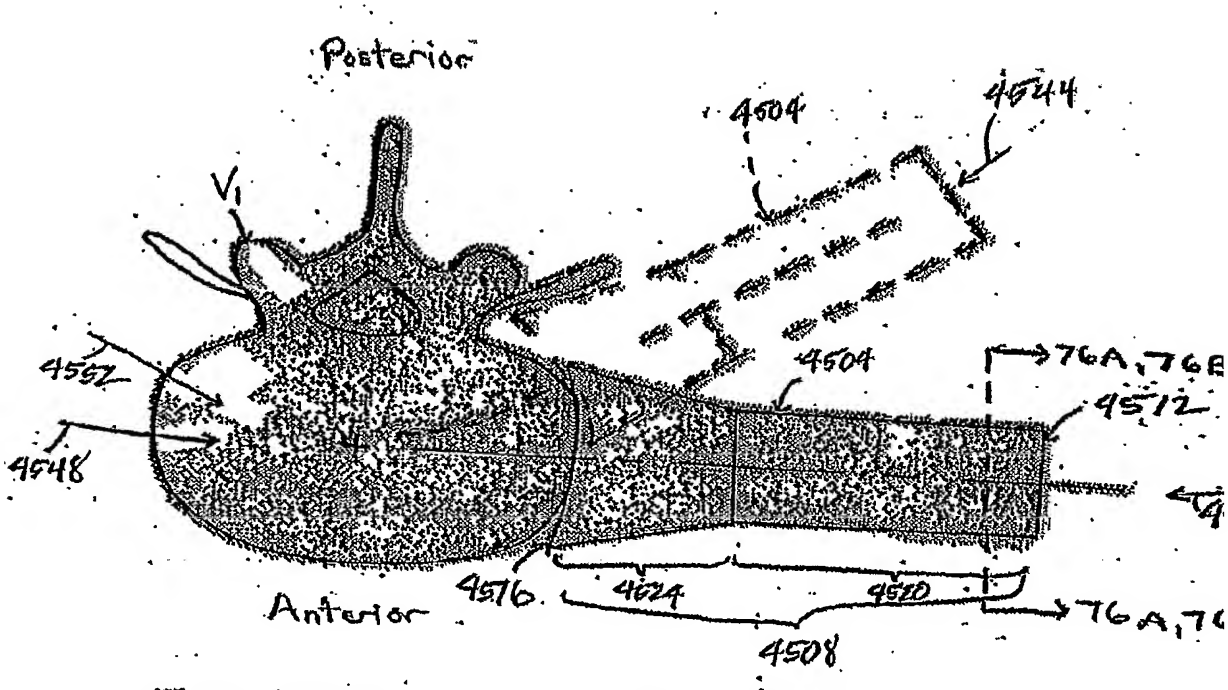


FIG. 76A

FIG. 76B

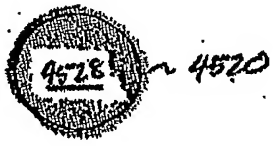


FIG. 77

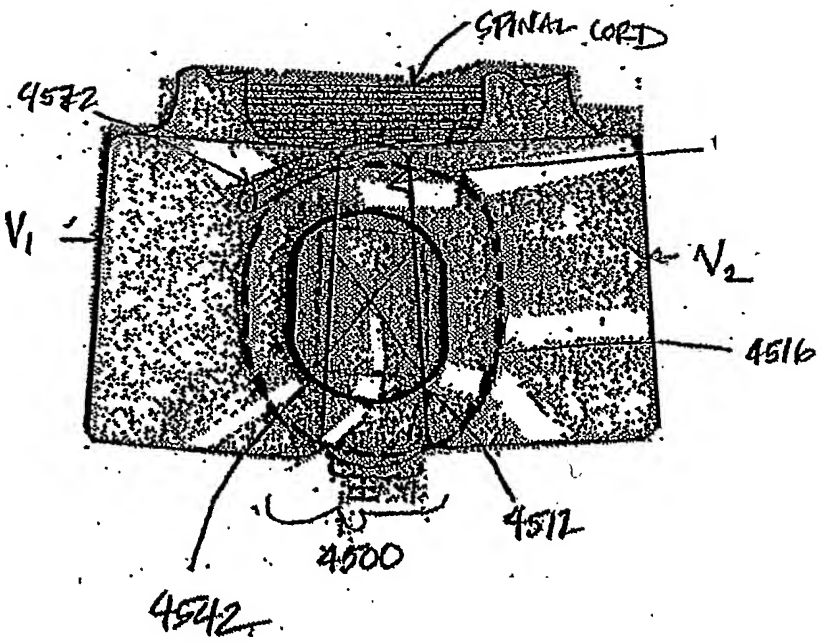


FIG. 78

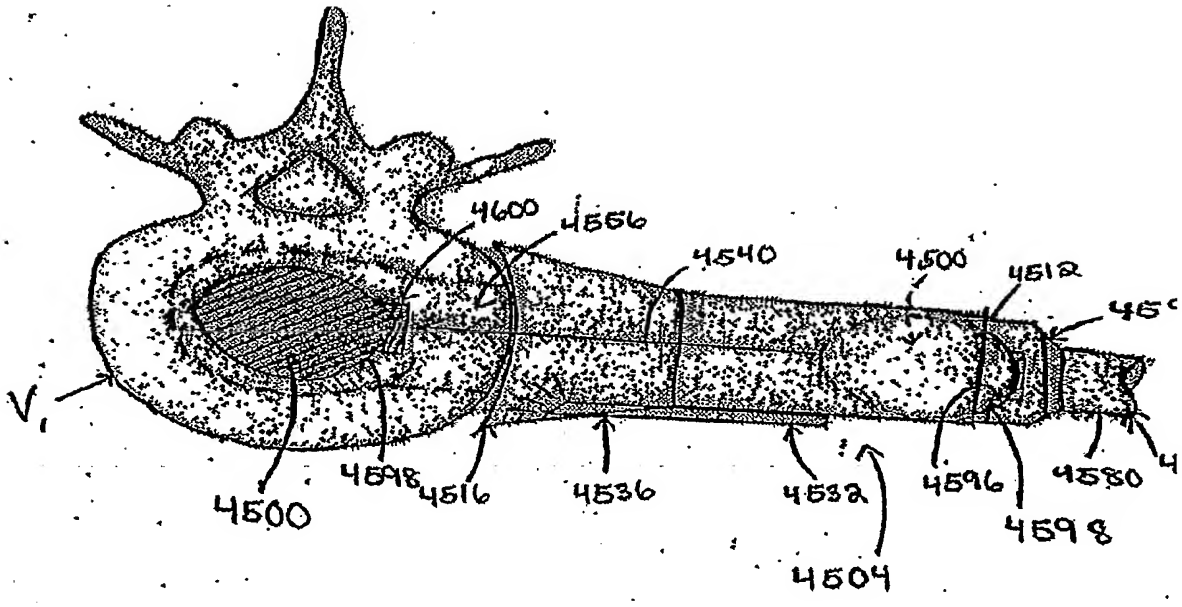

4600
4556
4540
4500
4512
4500
4598
4516
4536
4532
4596
4580
4598
4504

FIG. 79

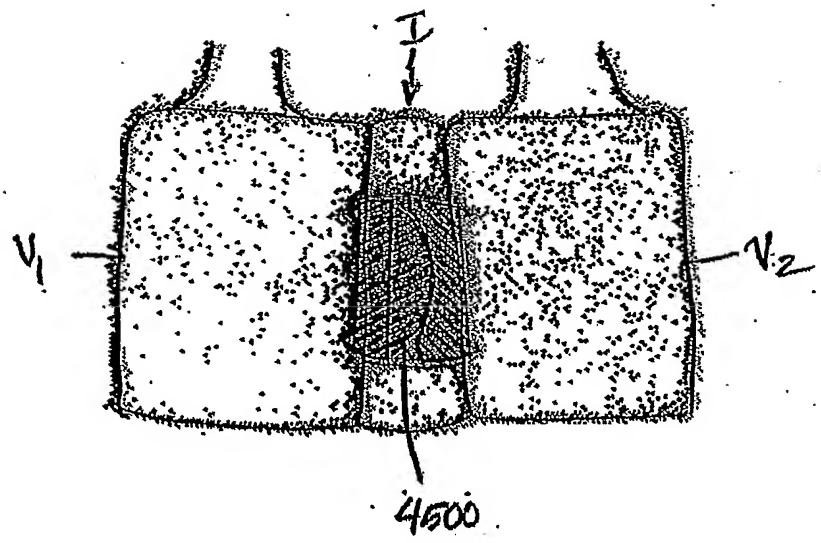


FIG. 8A

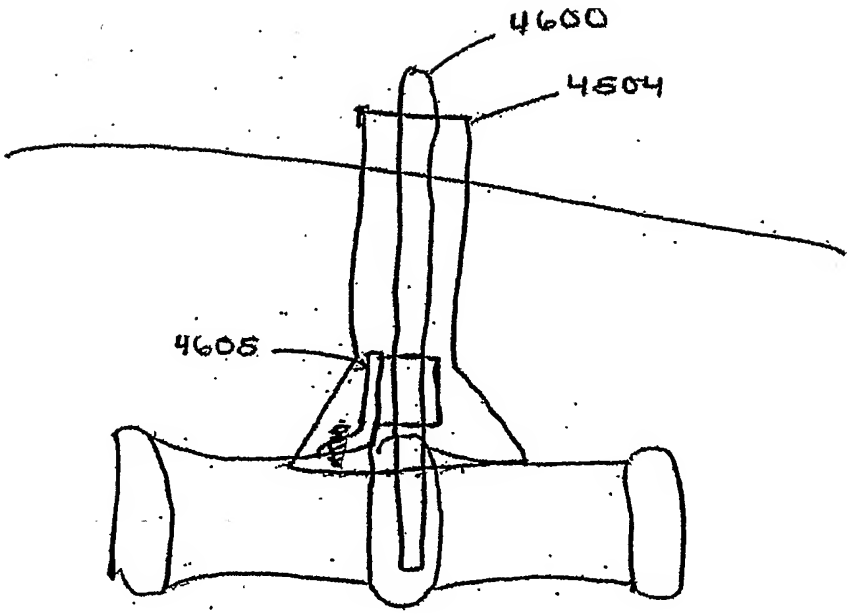


FIG 8.1

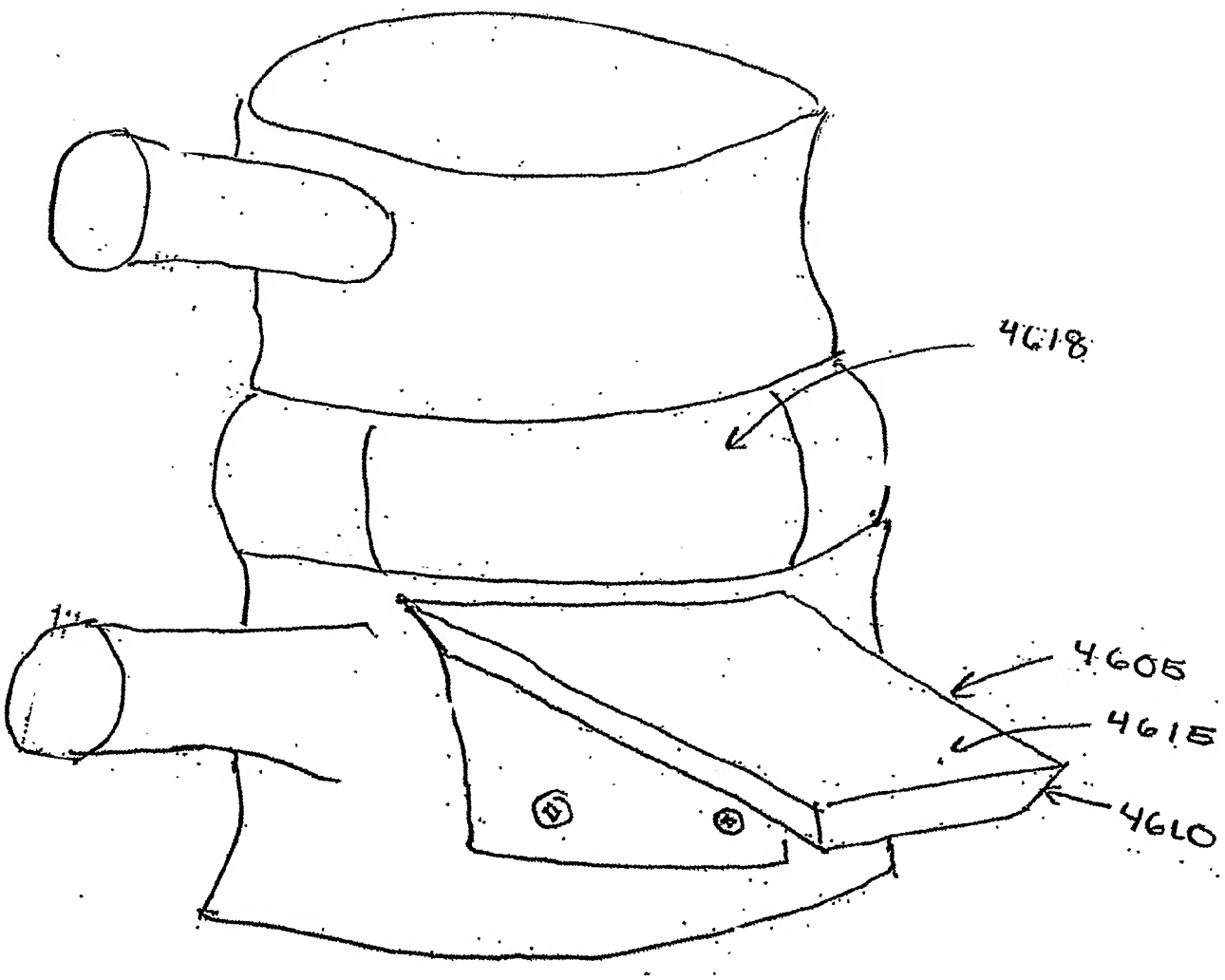


FIG. 82A

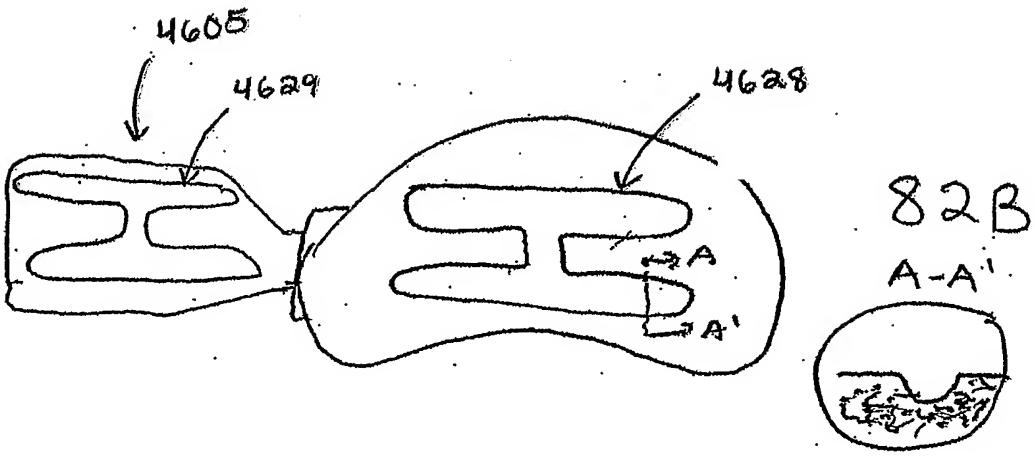
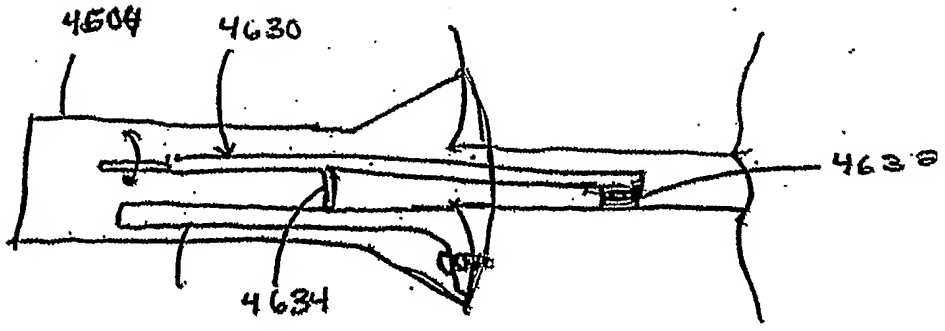


FIG. 82C



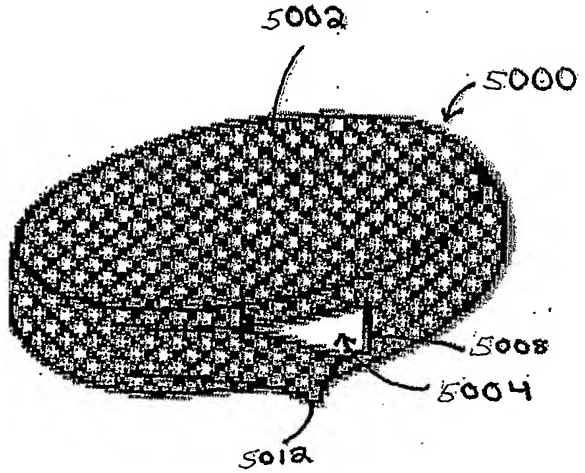


Fig. 83

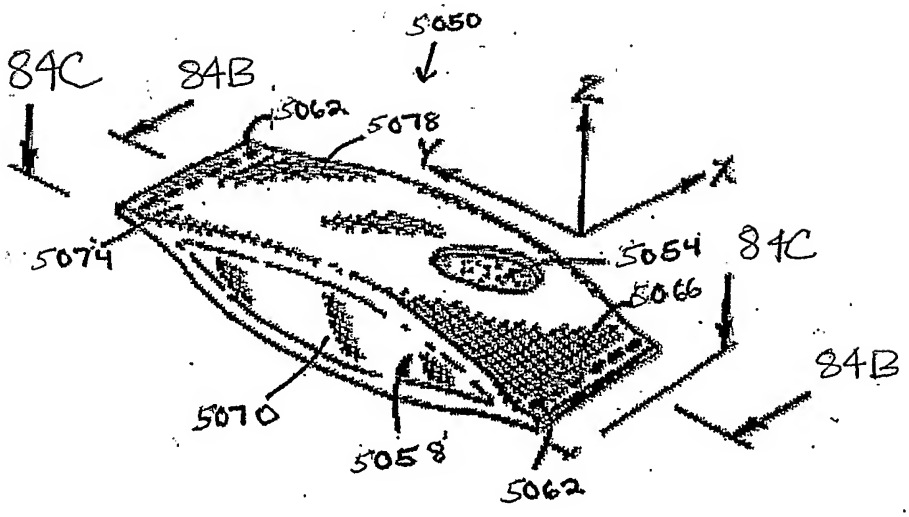


Fig. 84A

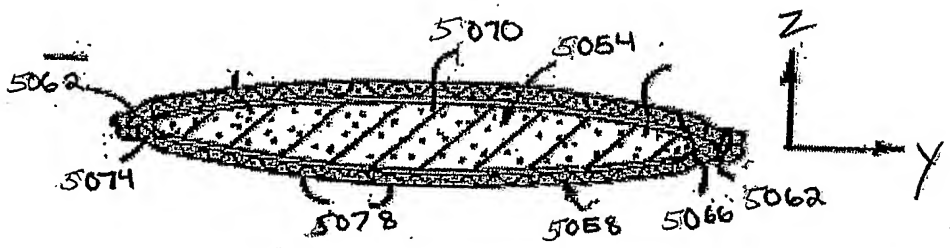


Fig. 84B

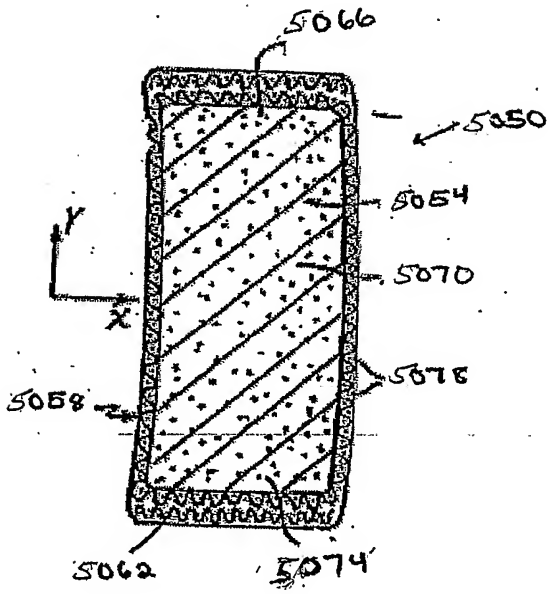


Fig. 84C

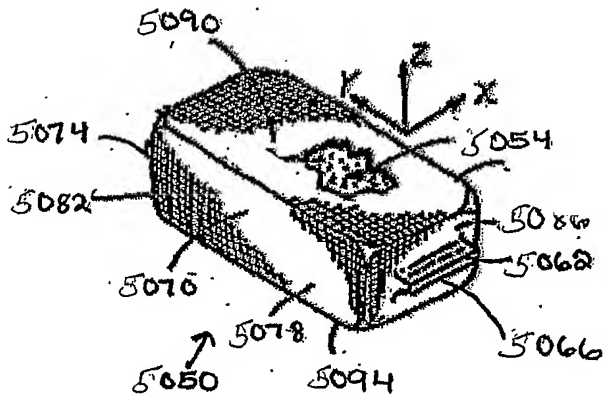


Fig. 85

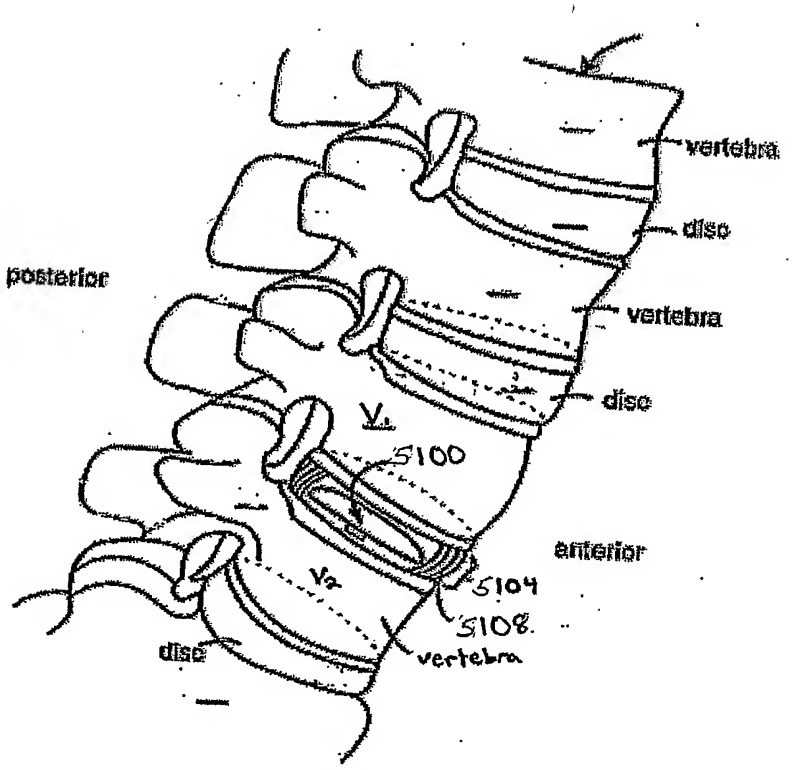

vertebra
disc
posterior
vertebra
disc
V1
5100
anterior
V2
5104
5108
disc
vertebra

Fig. 86

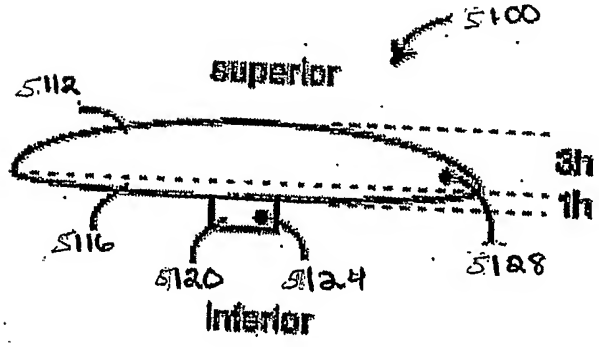

5100
superior
5112
3h
1h
5116
5120
5124
5128
Inferior

Fig. 87

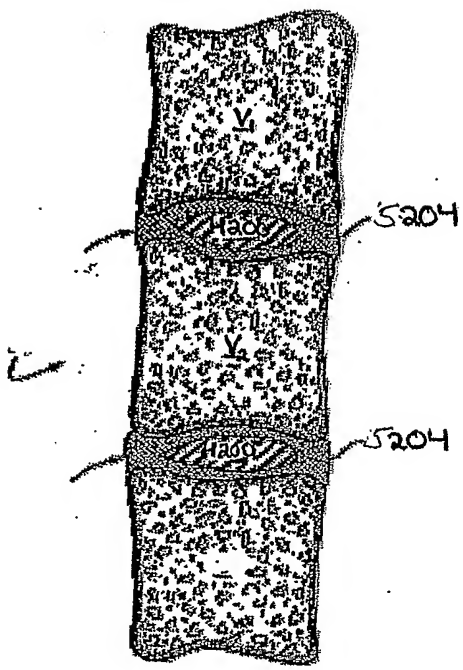


Fig. 88

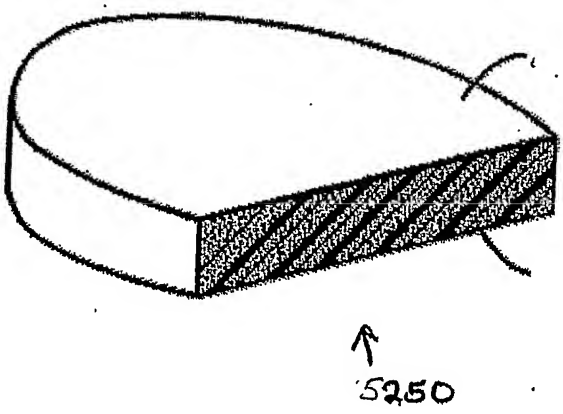


Fig. 89

Fig. 90

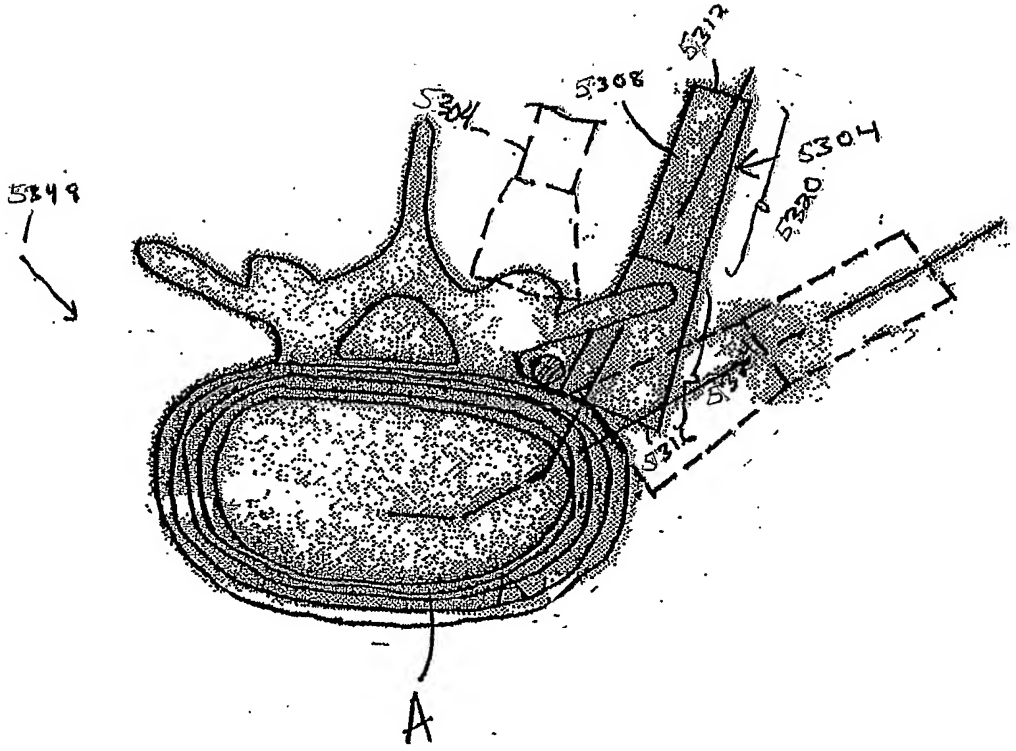


Fig. 91

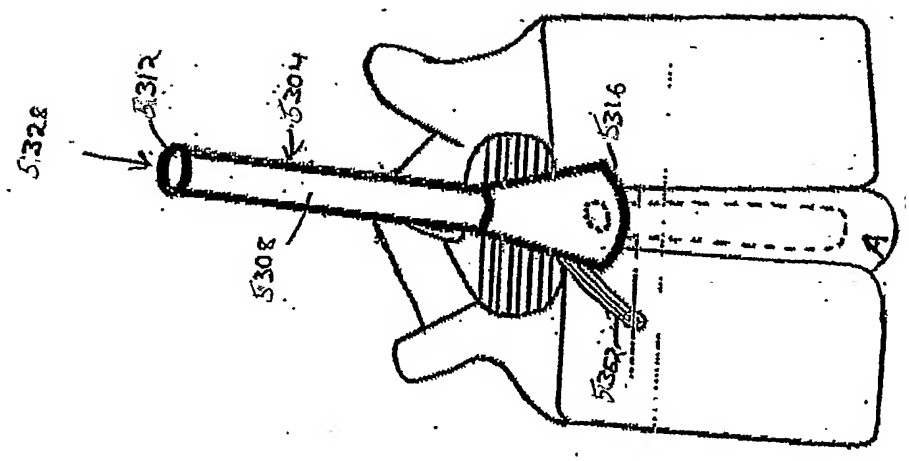


Fig. 92

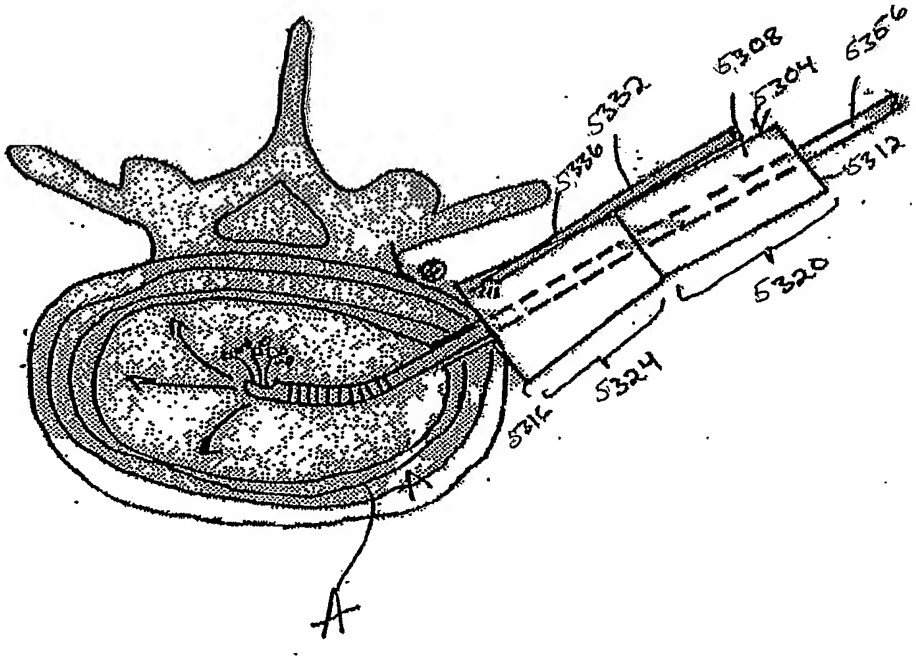


Fig. 9.3

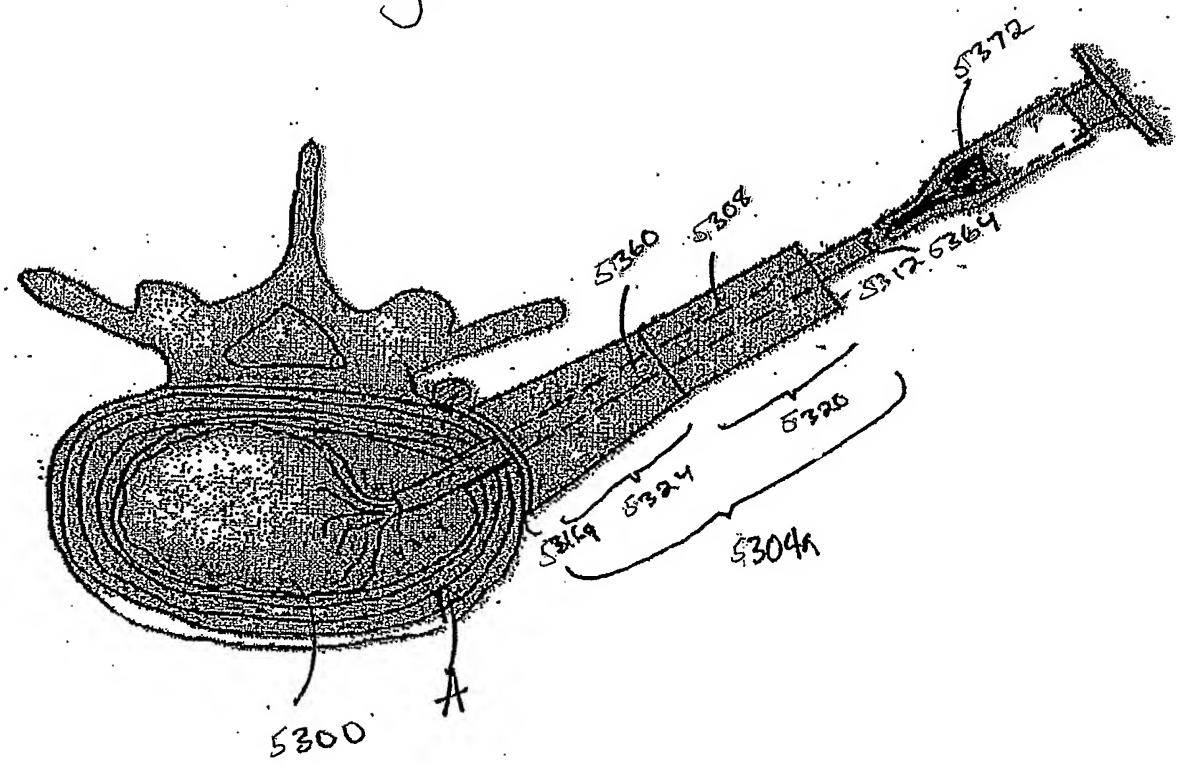


Fig. 94

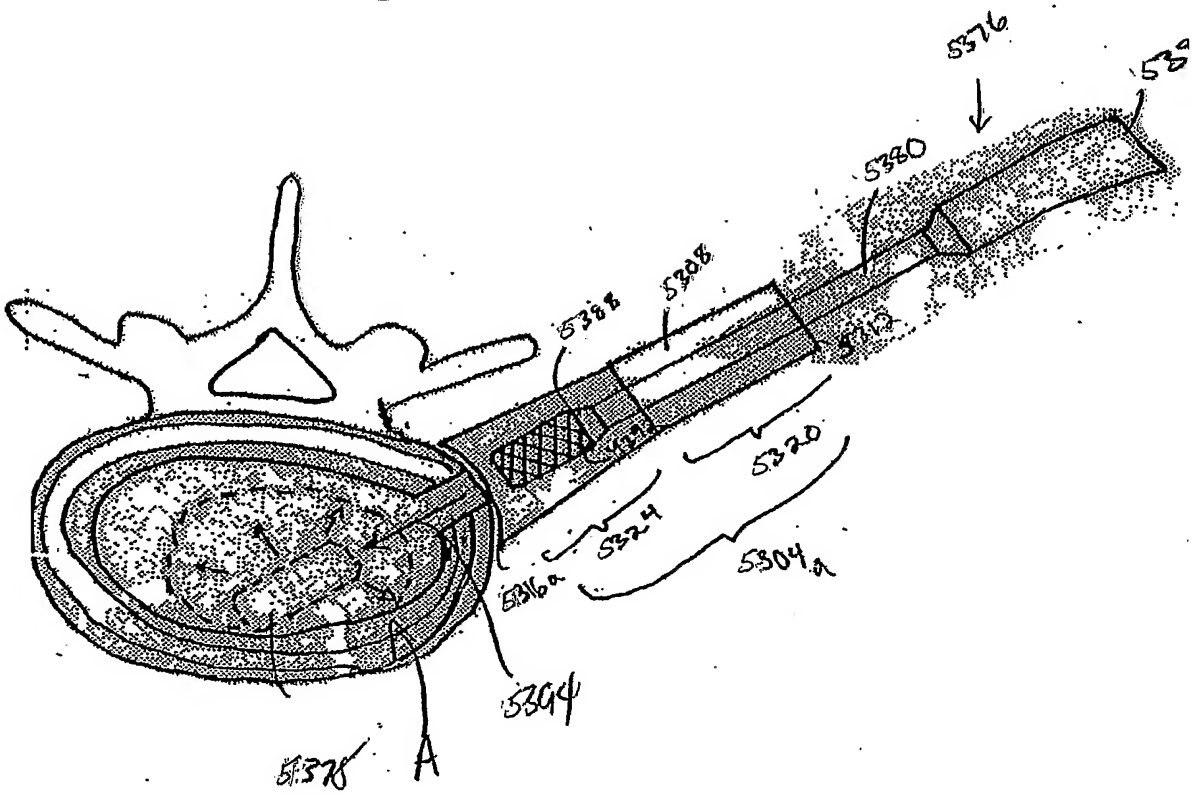
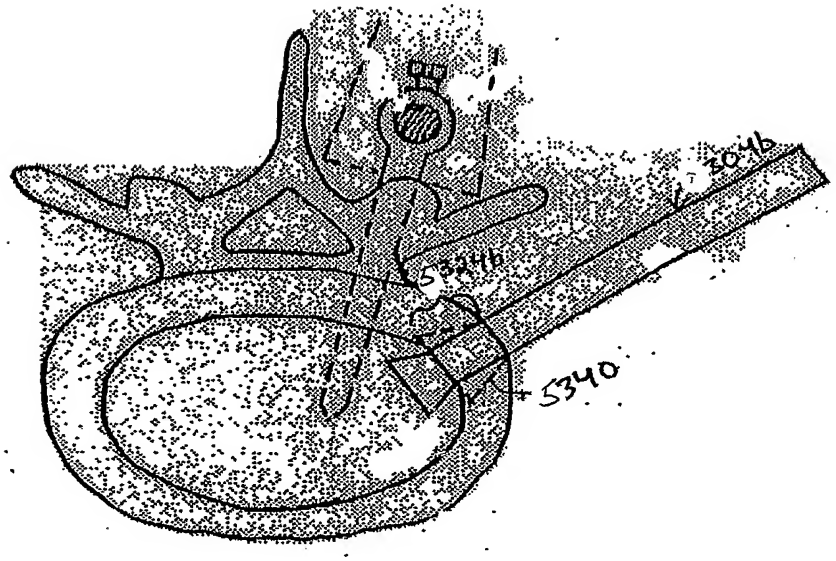


Fig. 95



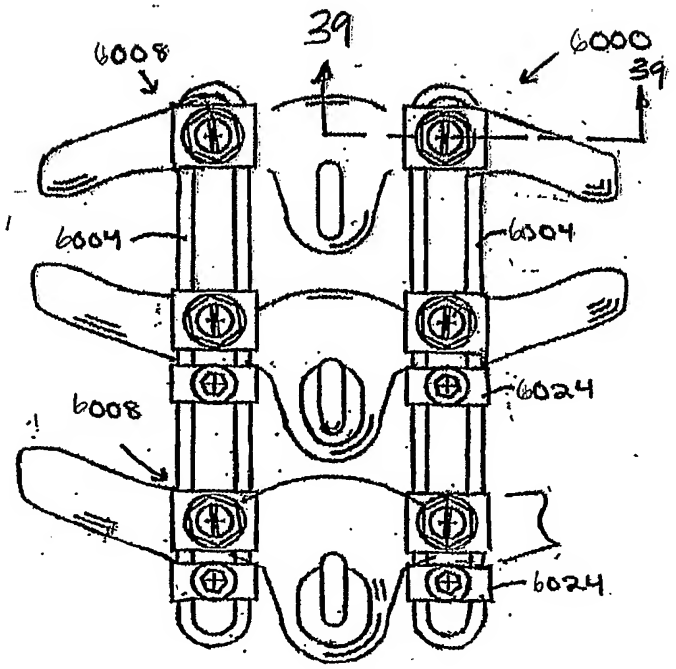


Fig. 96

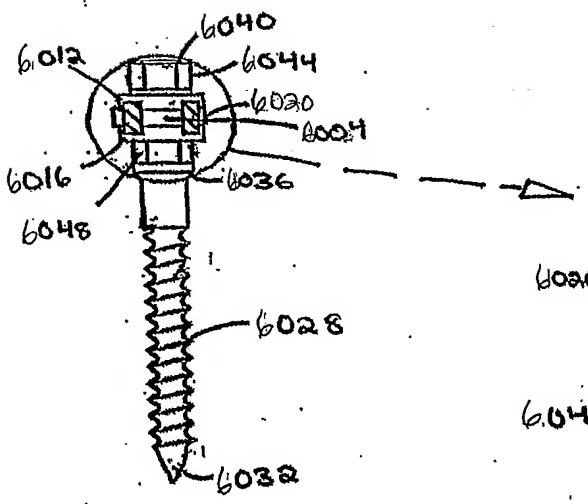


Fig. 97

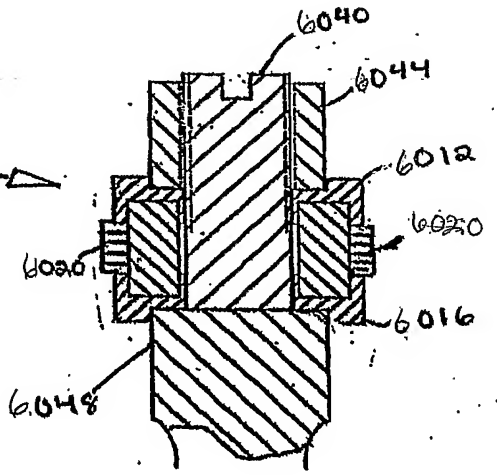
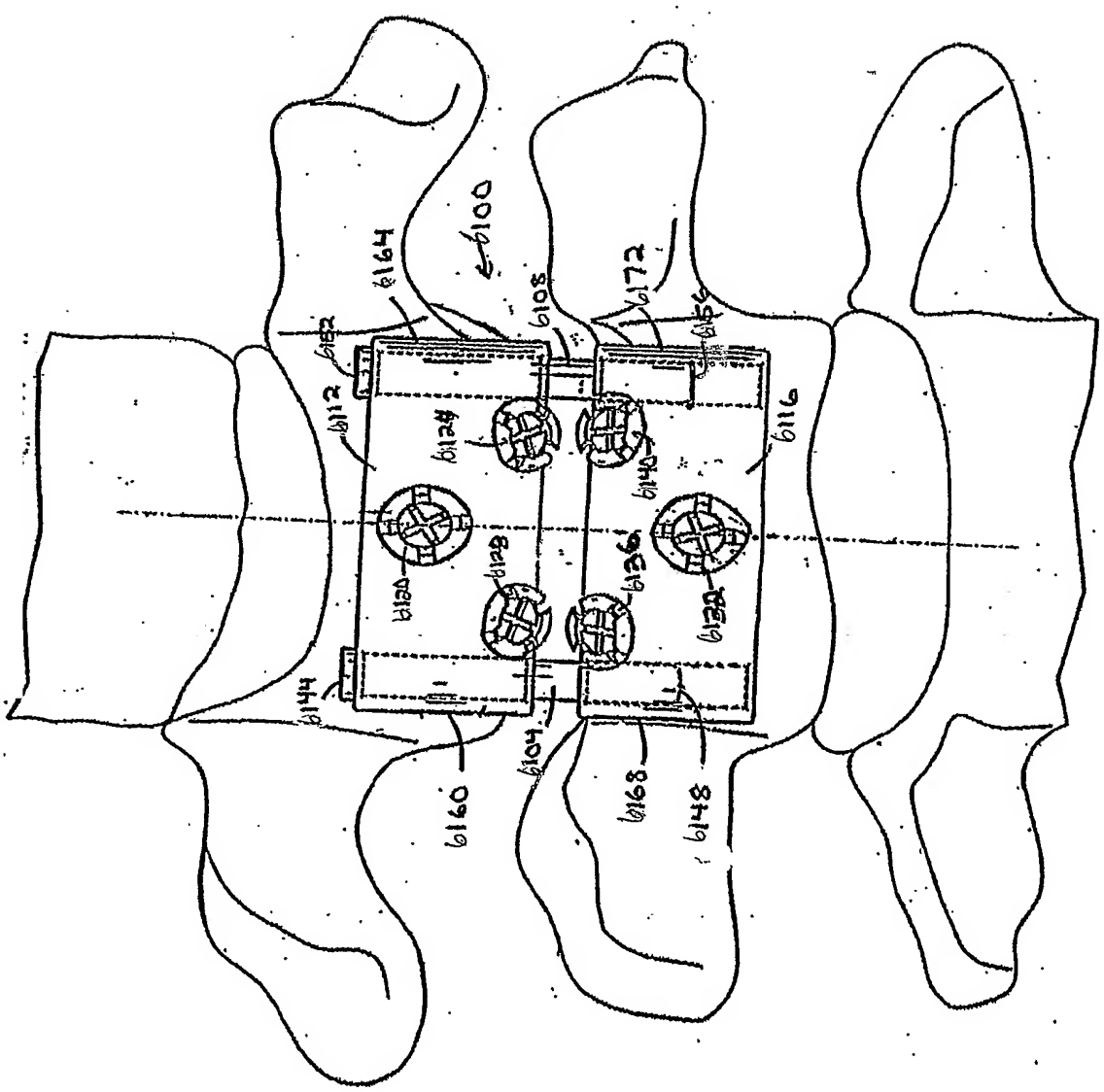


Fig. 98

Fig. 99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6164
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6148

Fig. 100

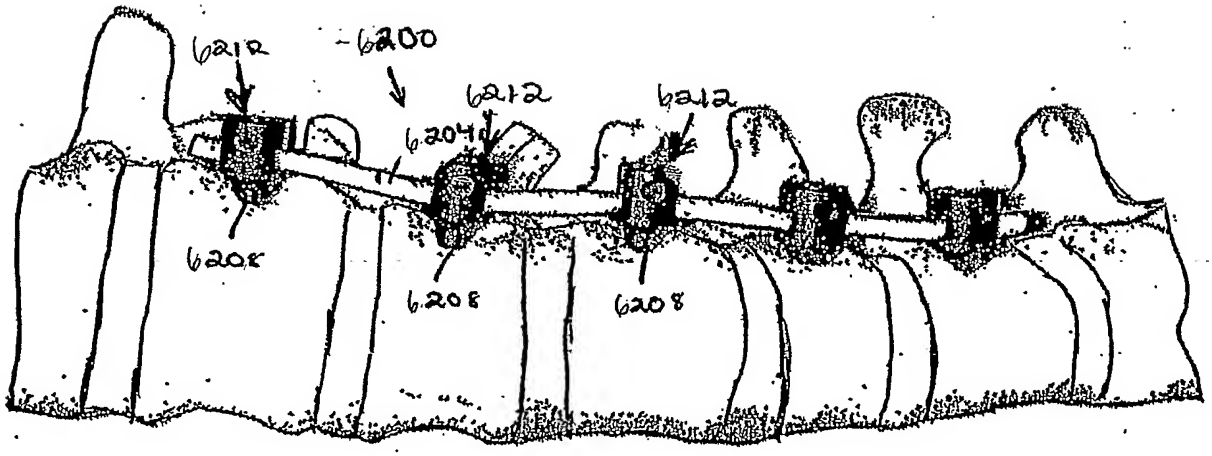
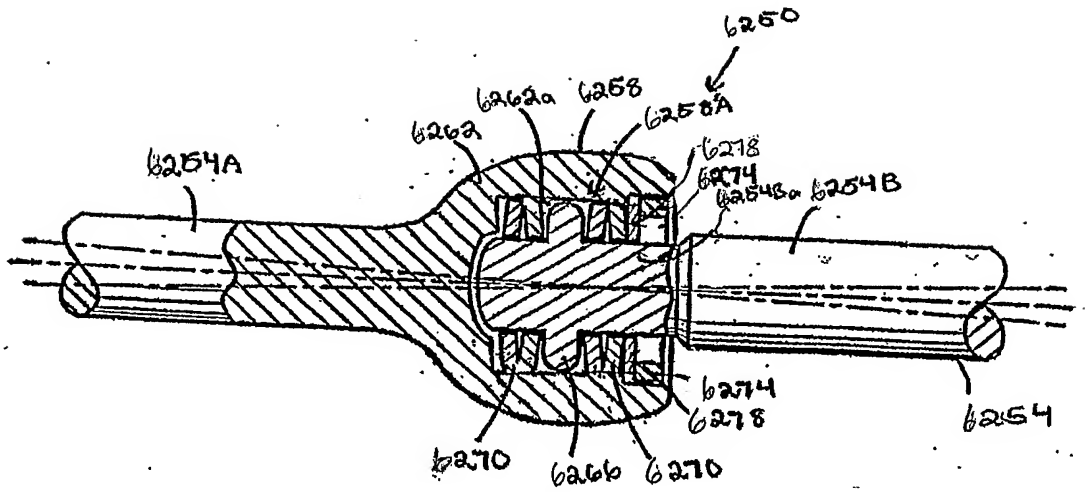


Fig. 101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6258A
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6254Ba
6254B
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6266
6270

Fig. 102

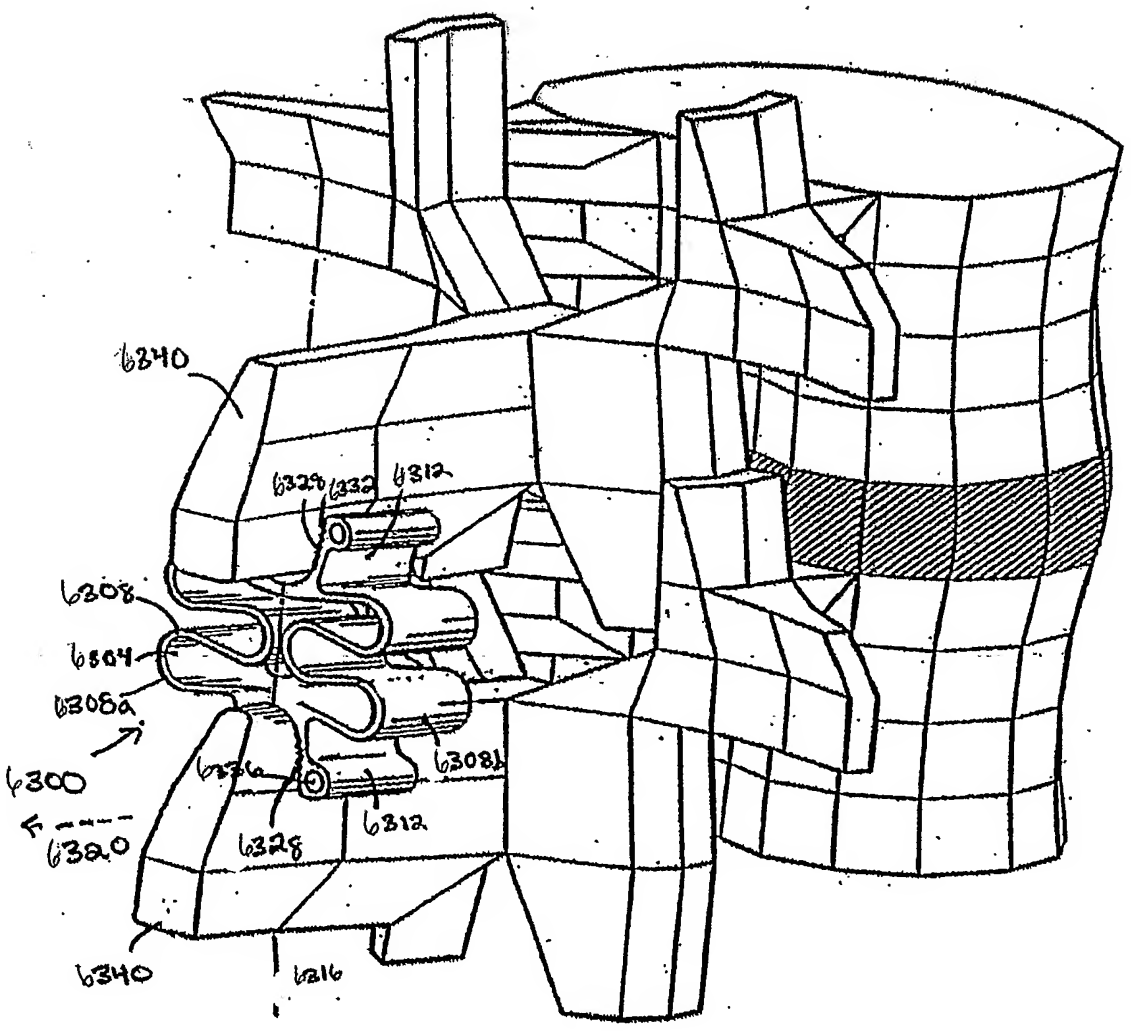
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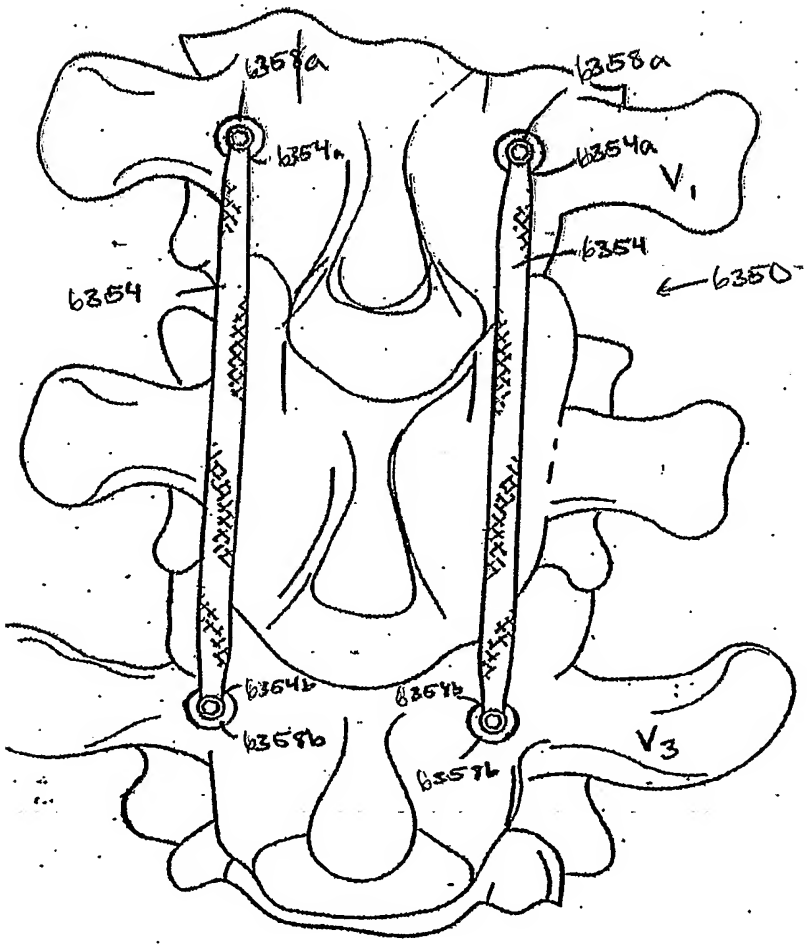
Fig. 103


6358a
6358a
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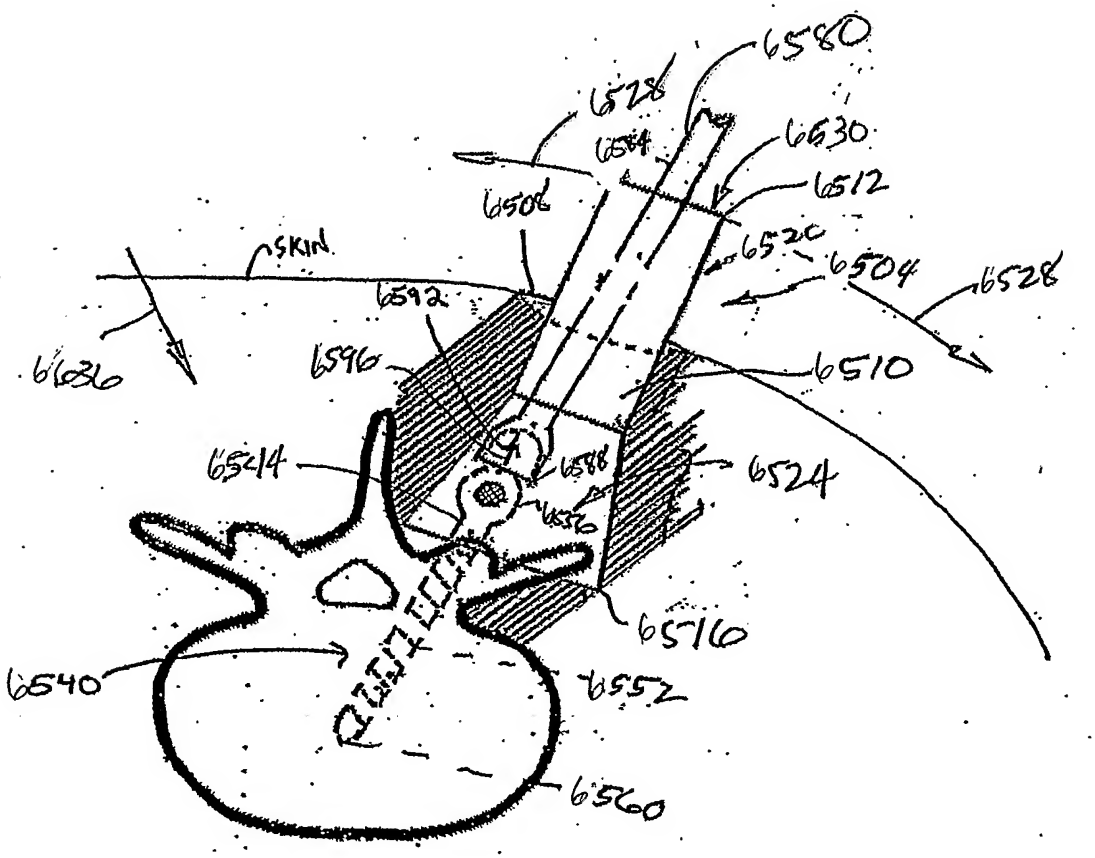
6354a
V1
6354
6350
6354
6354b
6354b
6358b
6358b
V3

Fig. 104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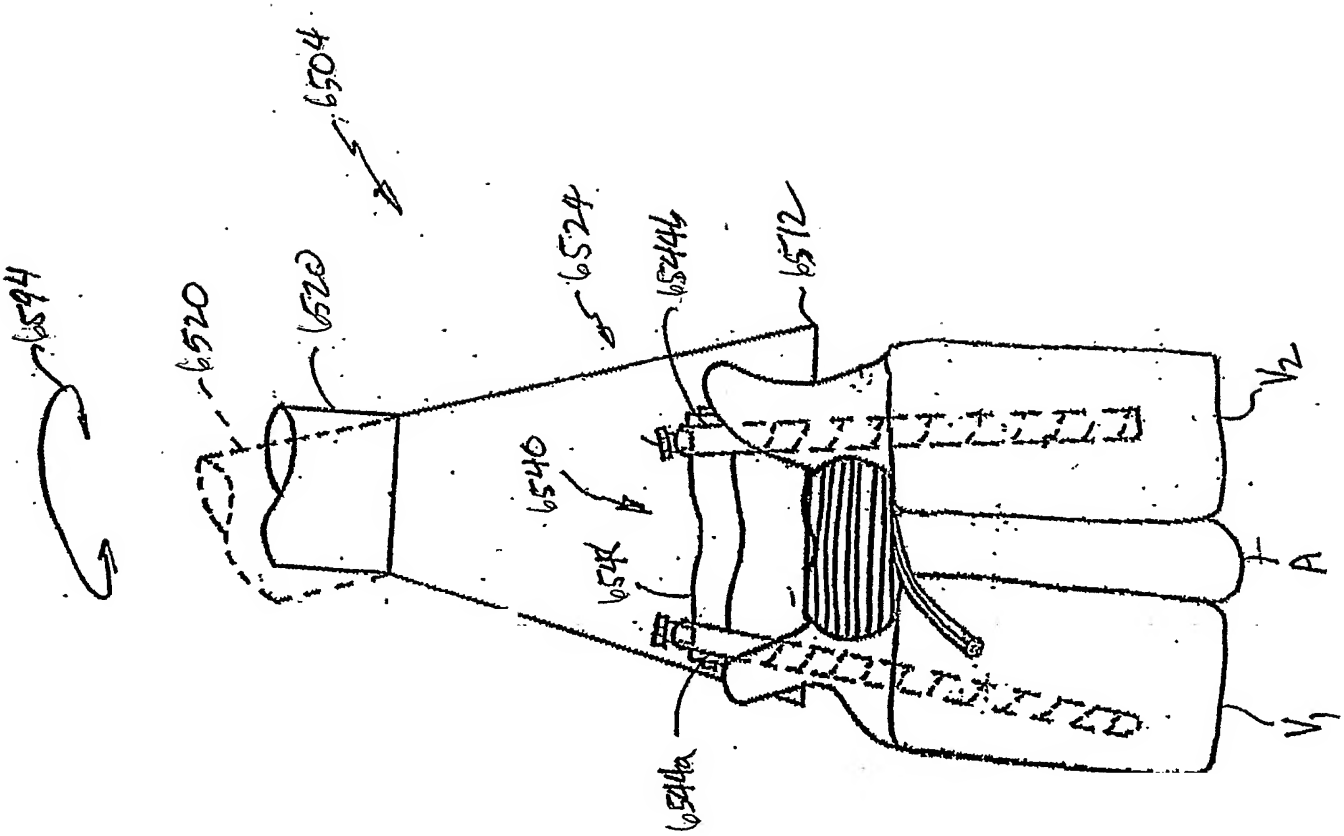


Fig. 105

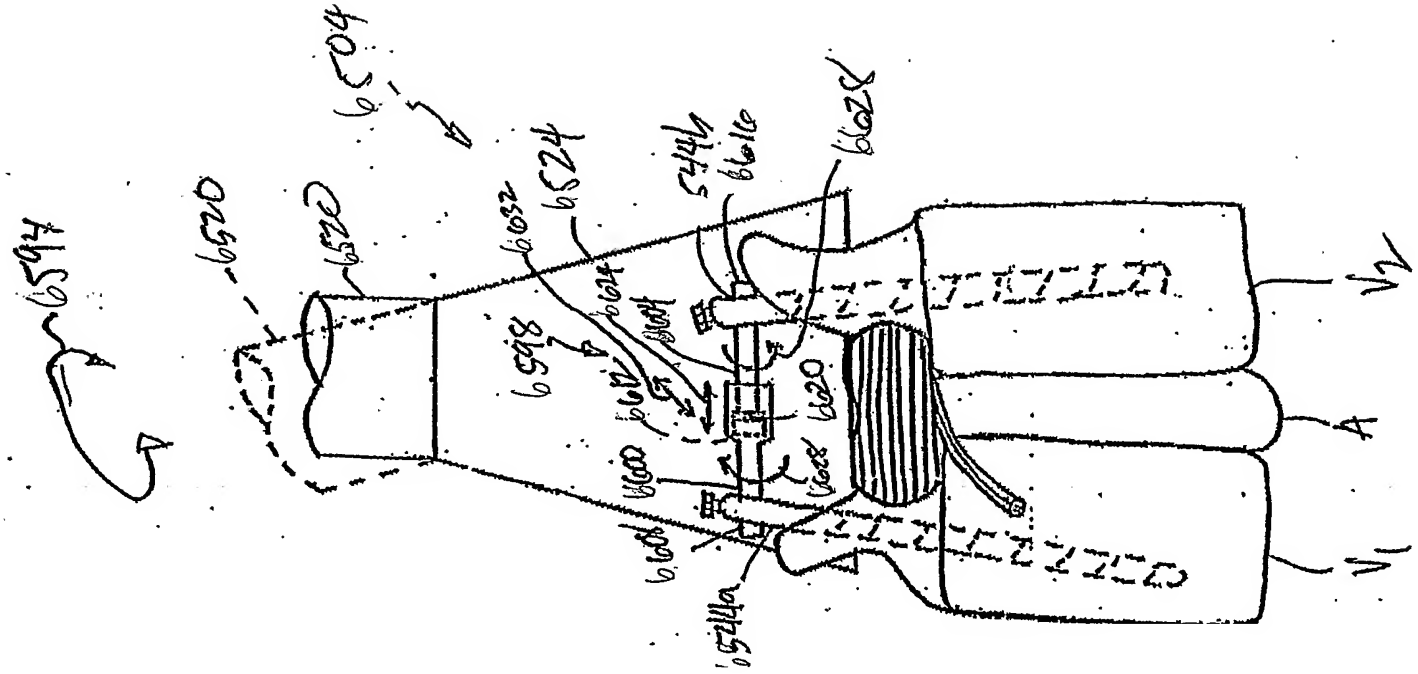


Fig. 10b

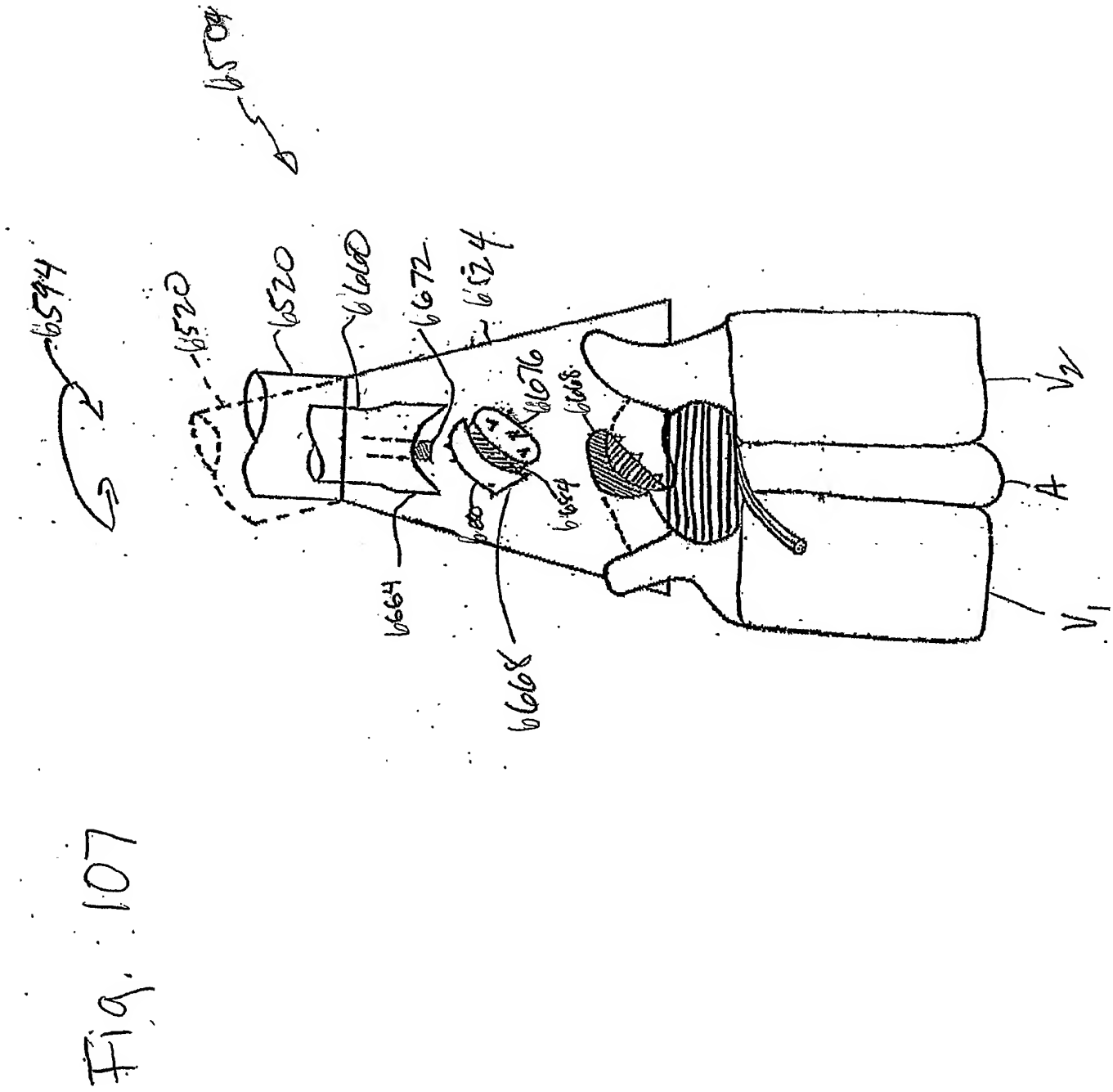


Fig. 107

Fig. 108

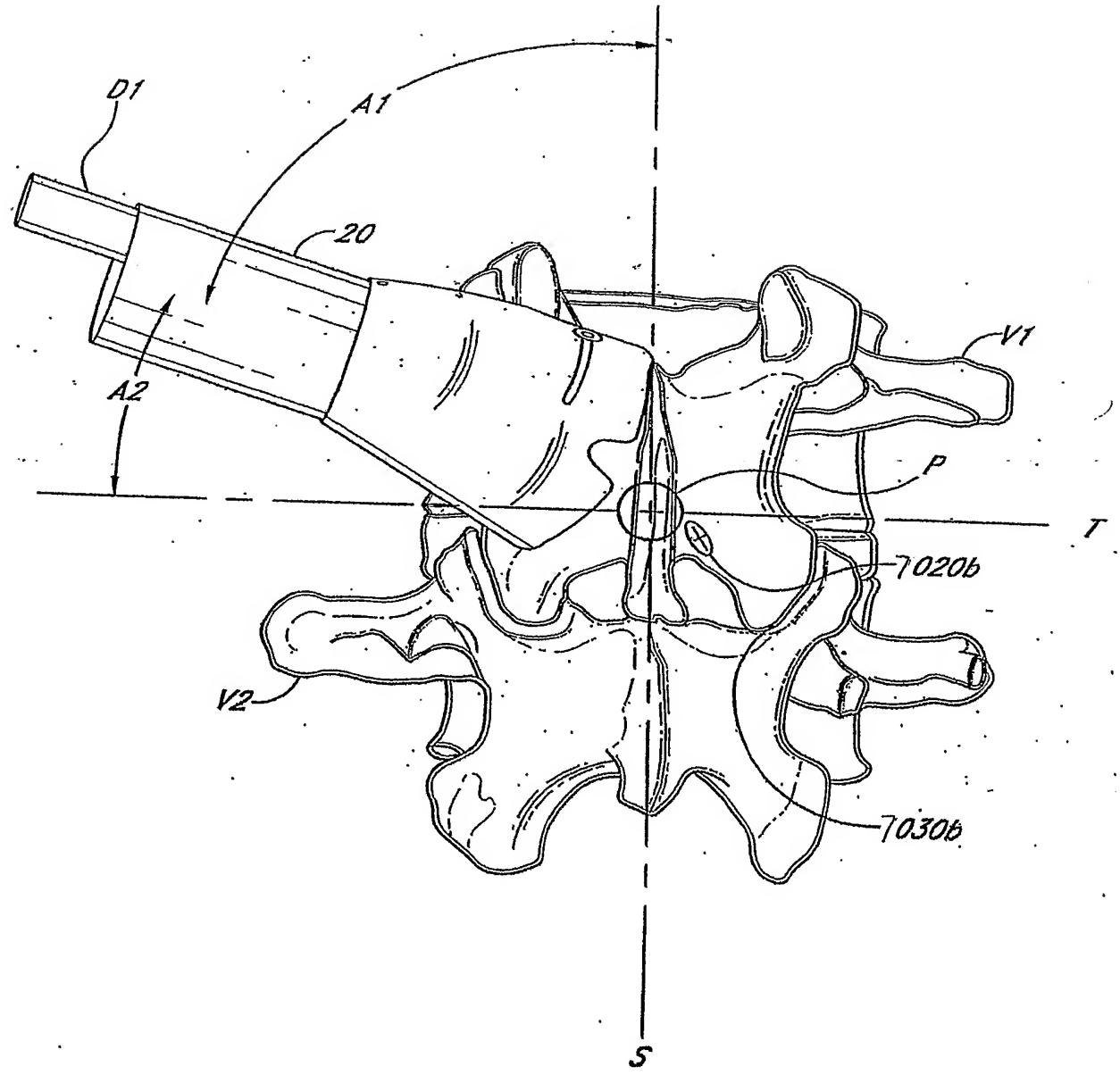
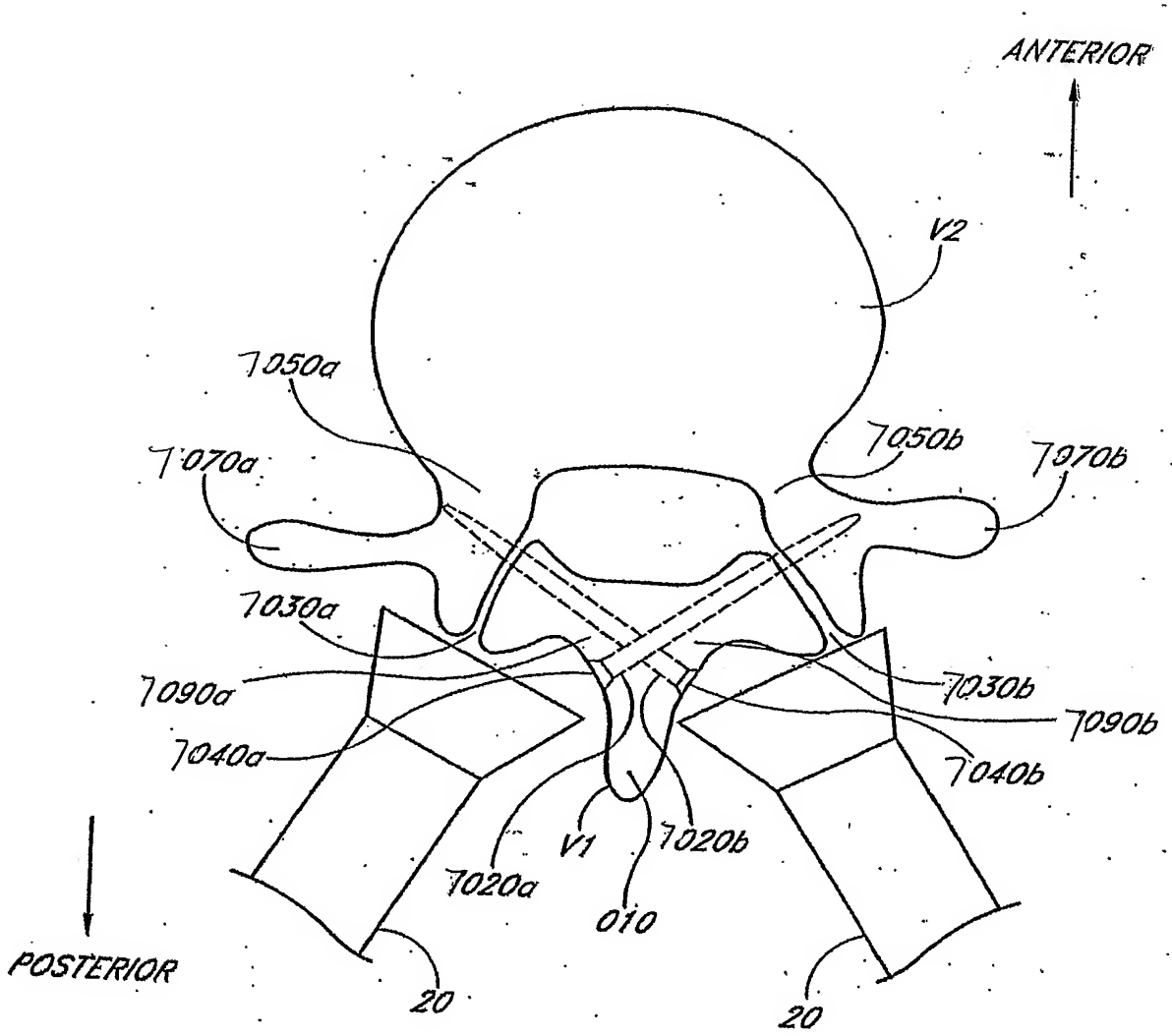


Fig. 109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V2
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7040b
V1
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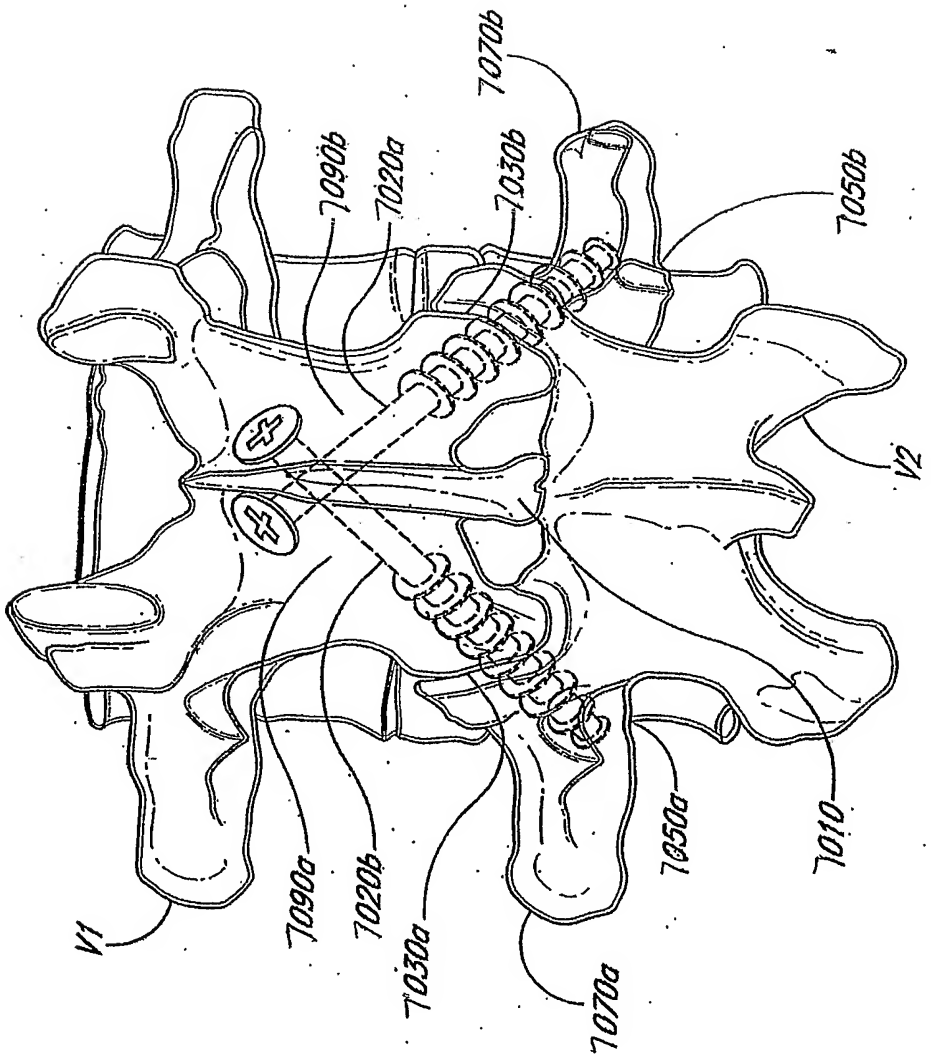
7020a
010
POSTERIOR
20
20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7050b
V2
V1
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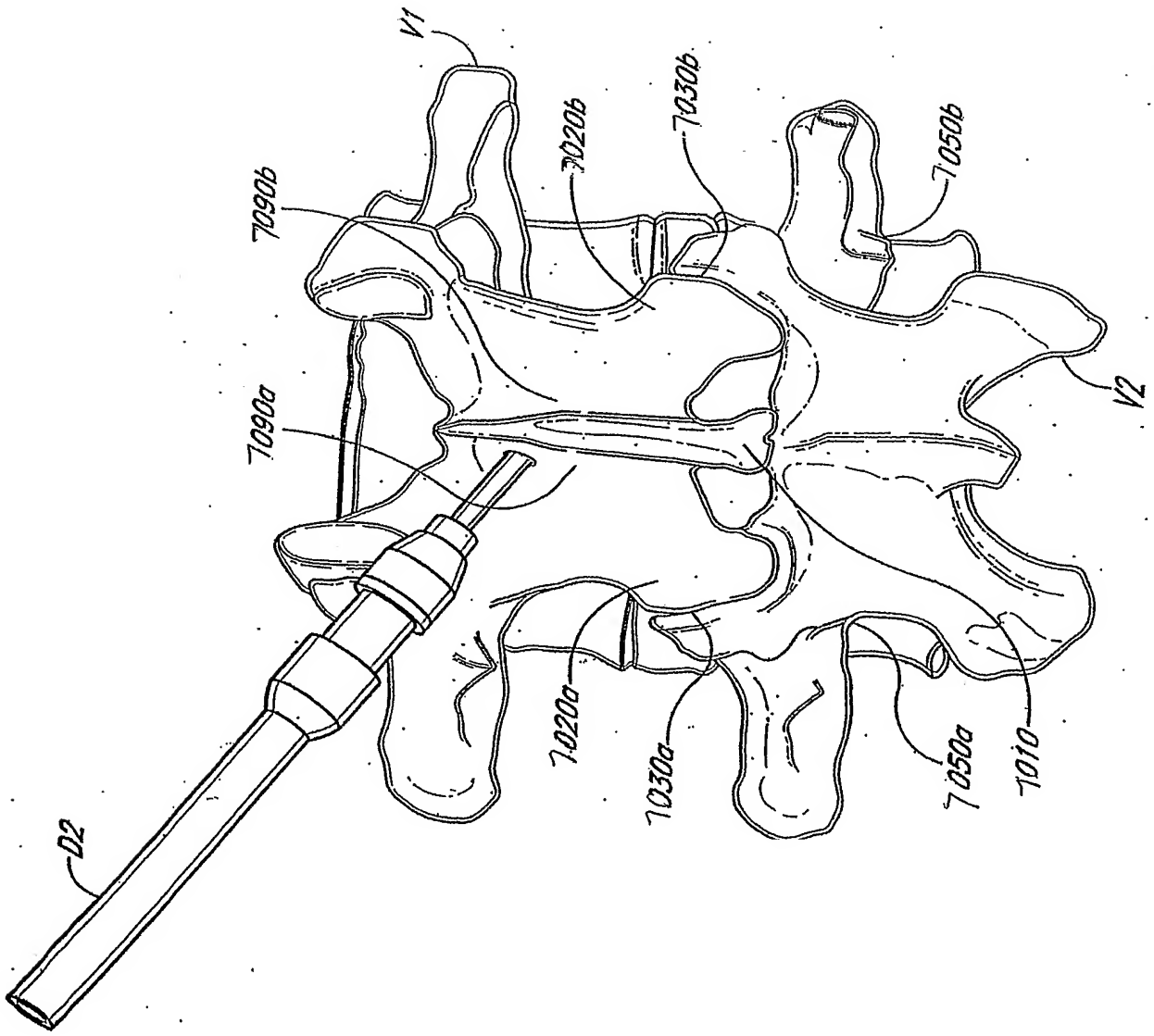
7020b
7030a
7070a
7050a
7010

Fig. 11D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7030a
7050a
1010
D2

Fig. 111

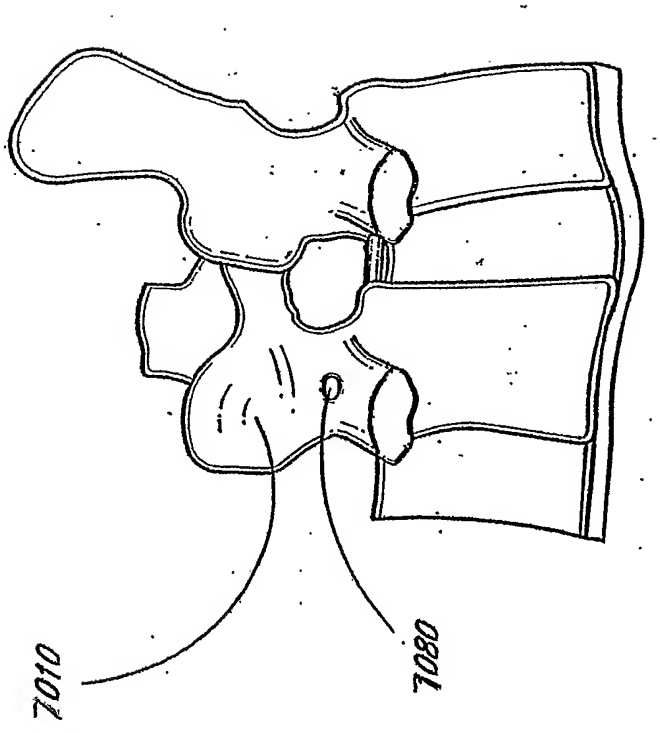


Fig. 112

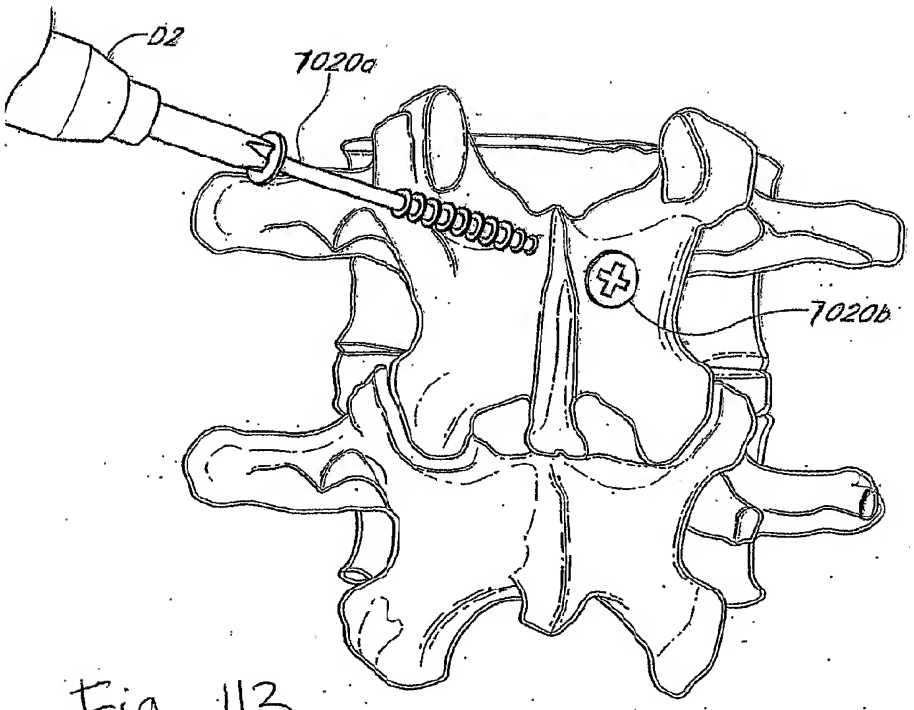


Fig. 113

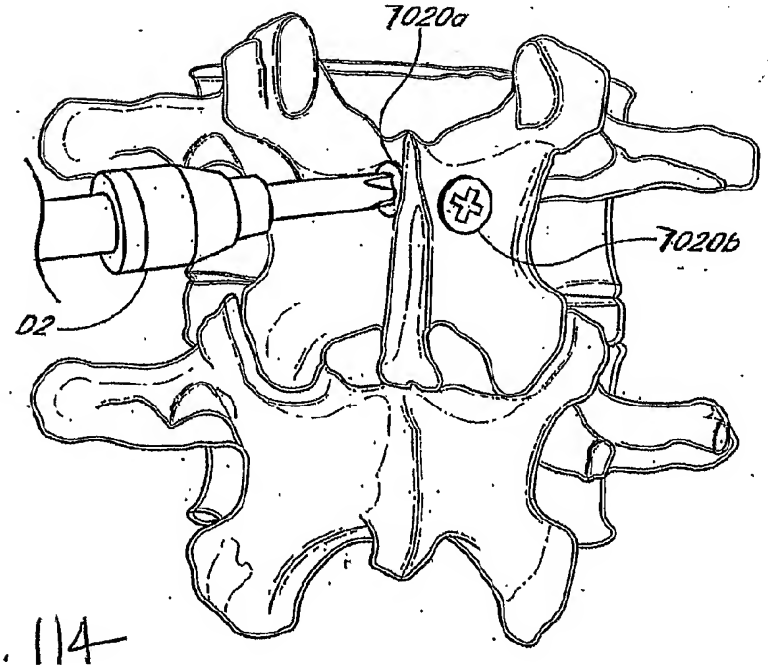
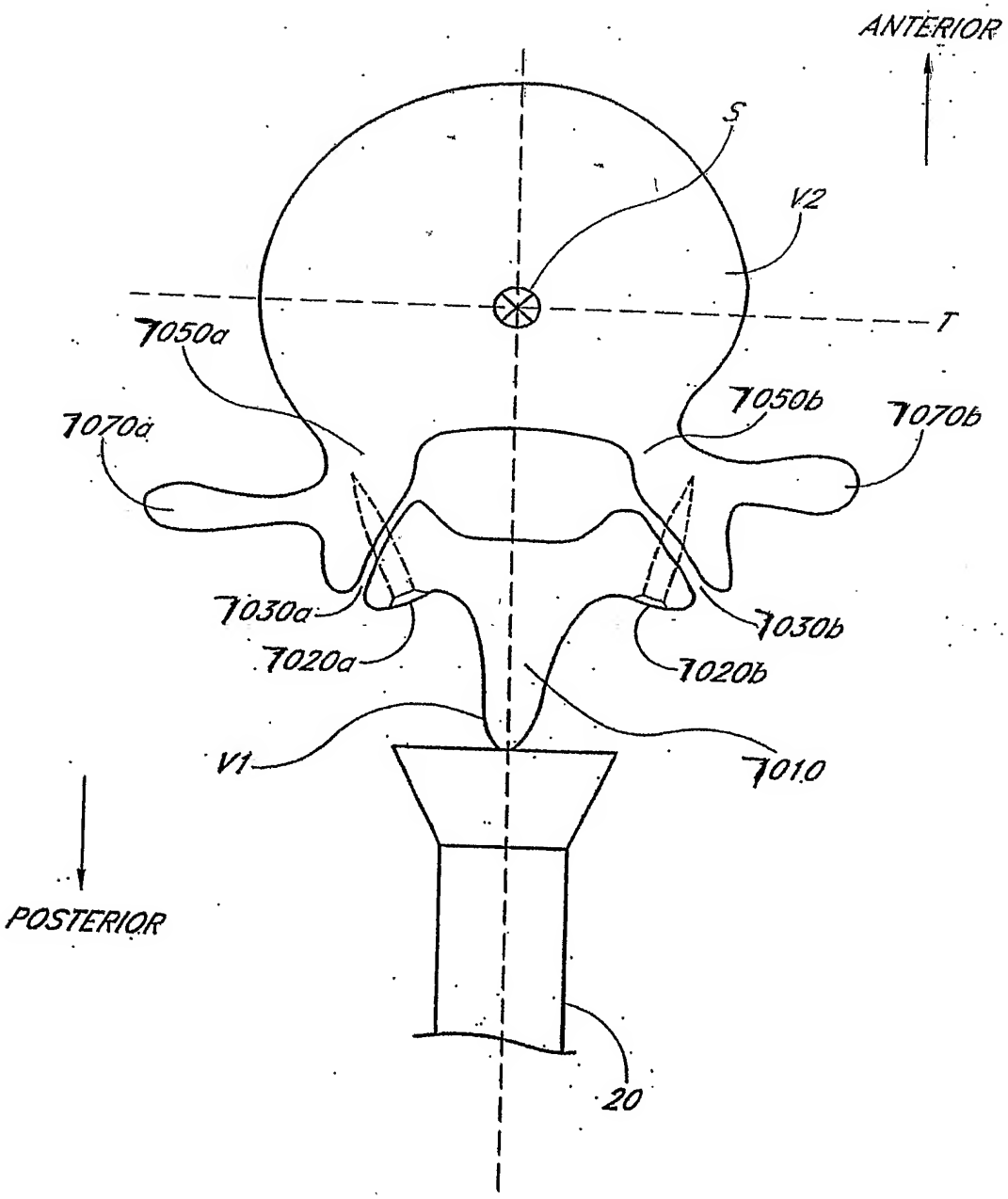


Fig. 114

Fig. 115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POSTERIOR
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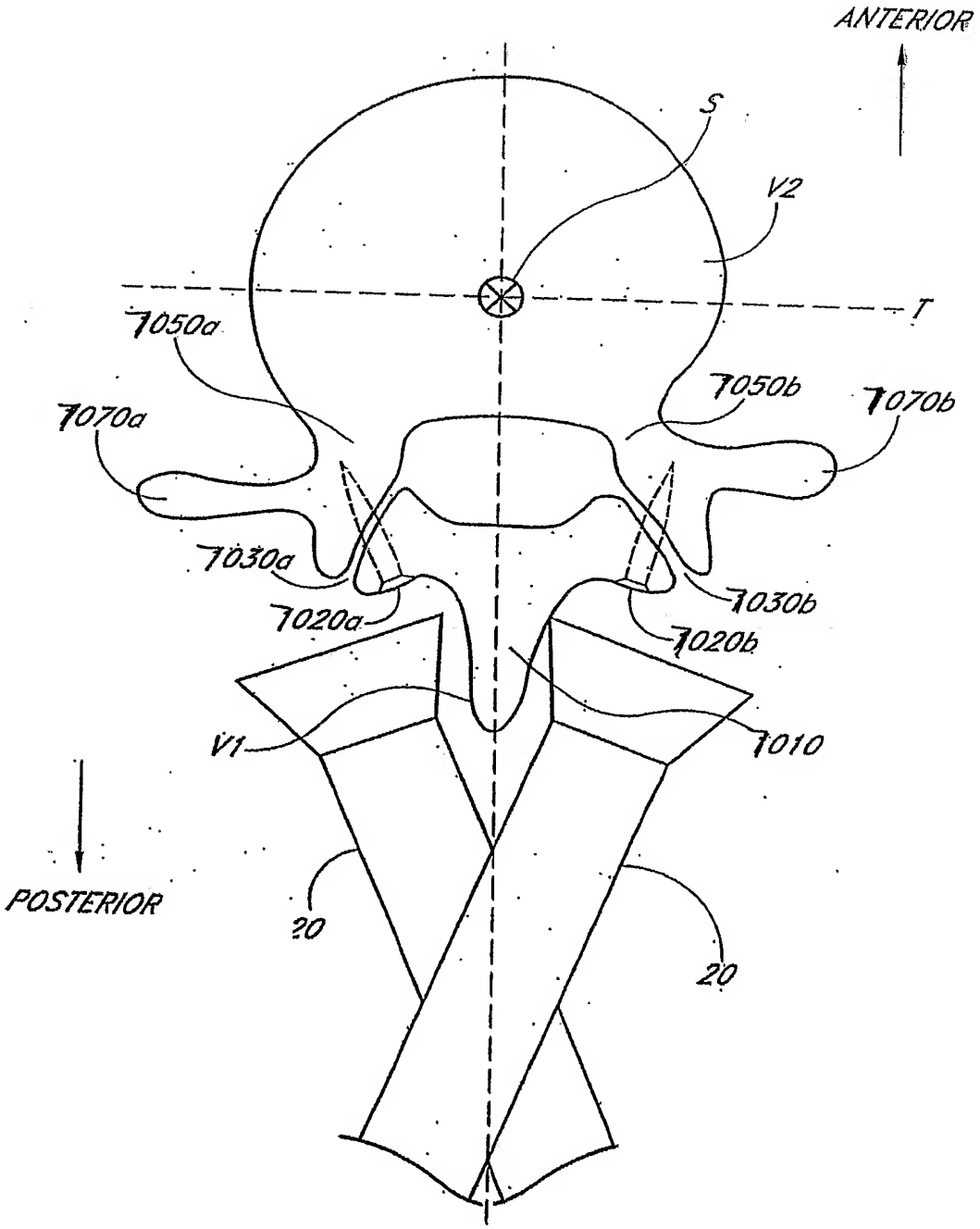
Fig. 116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V1
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POSTERIOR
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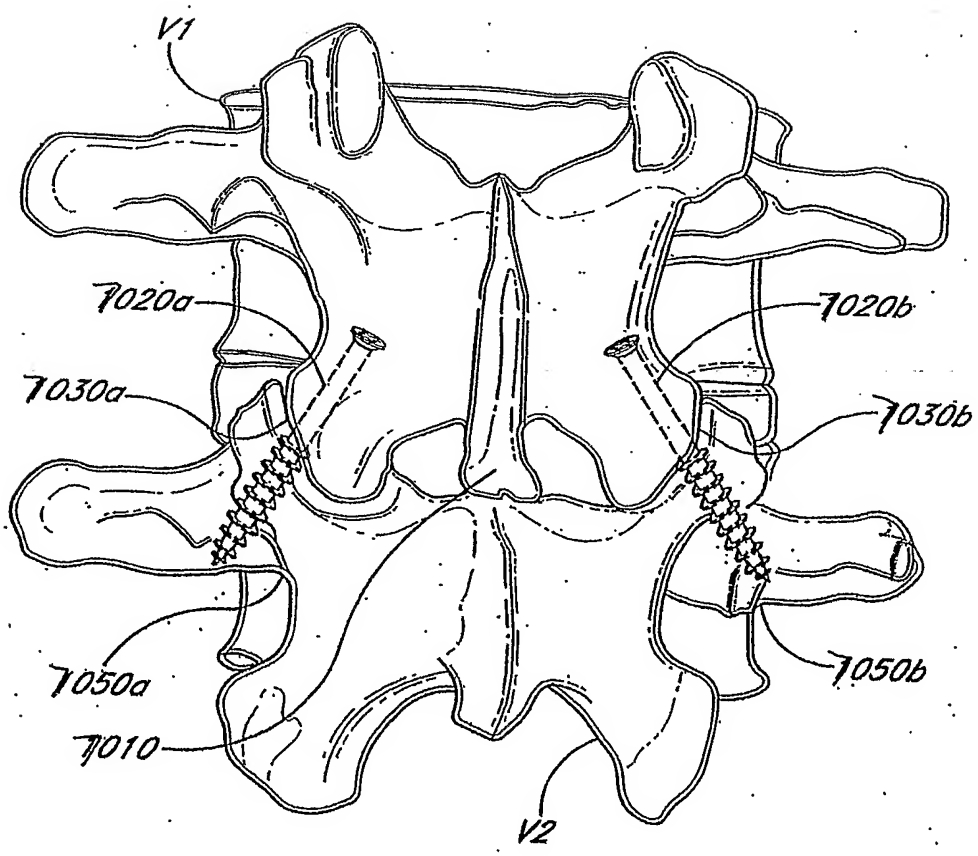
Fig. 117



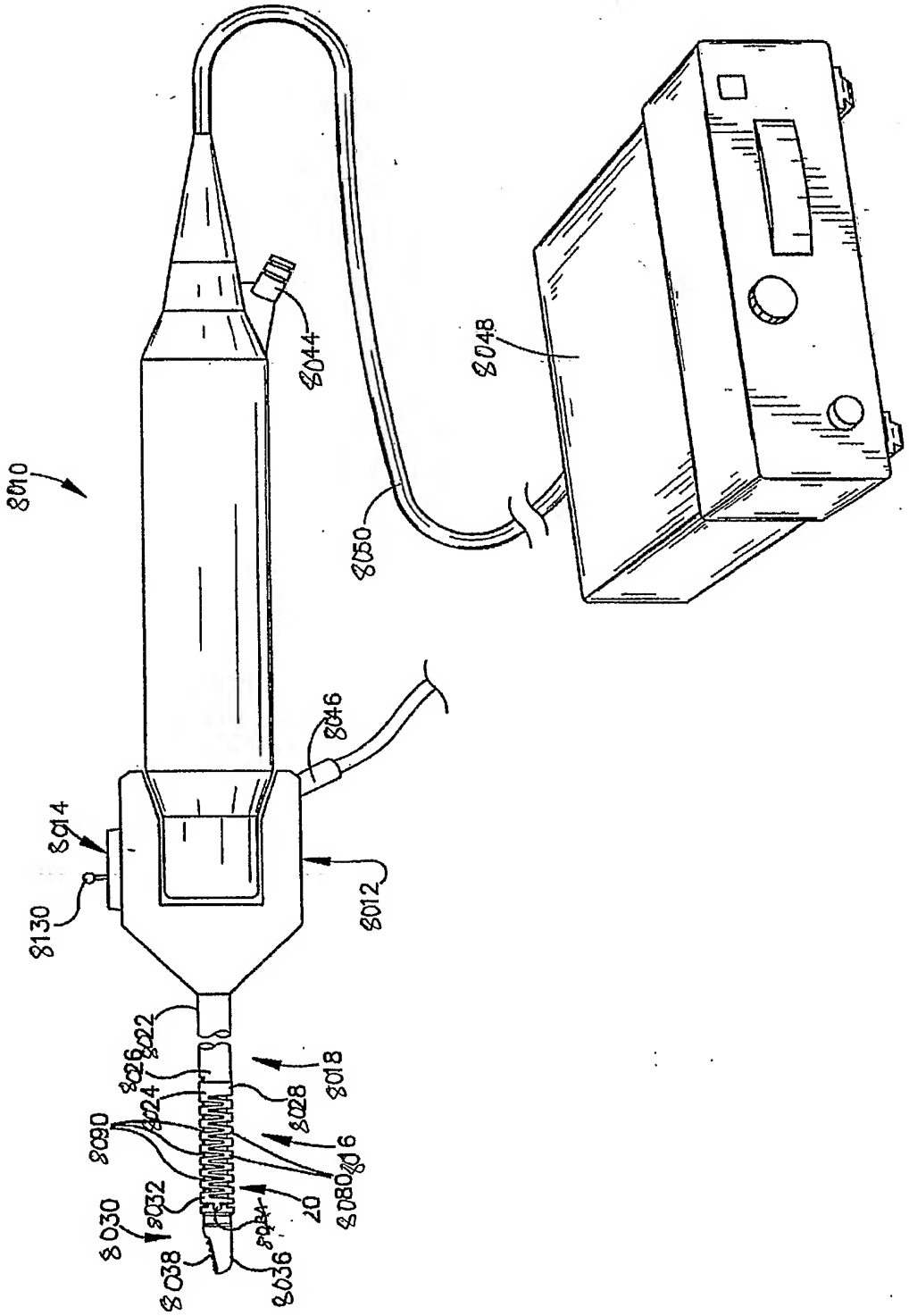

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Fig. 118

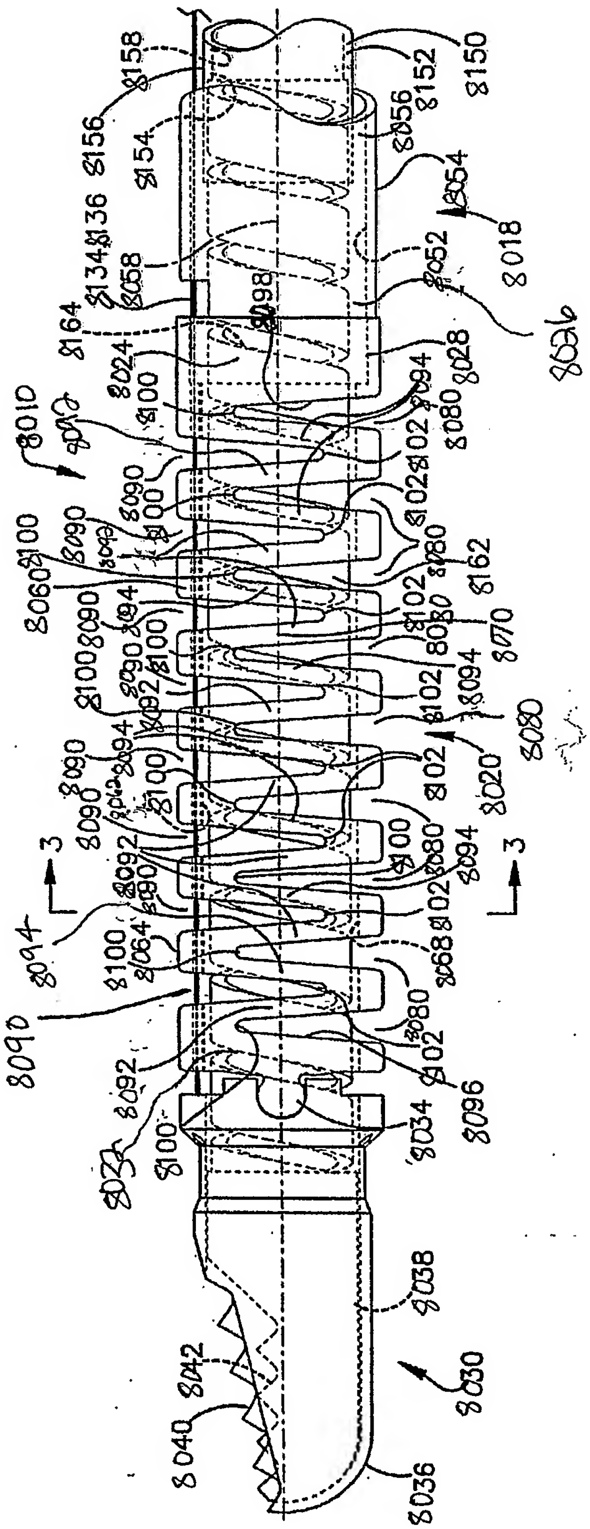
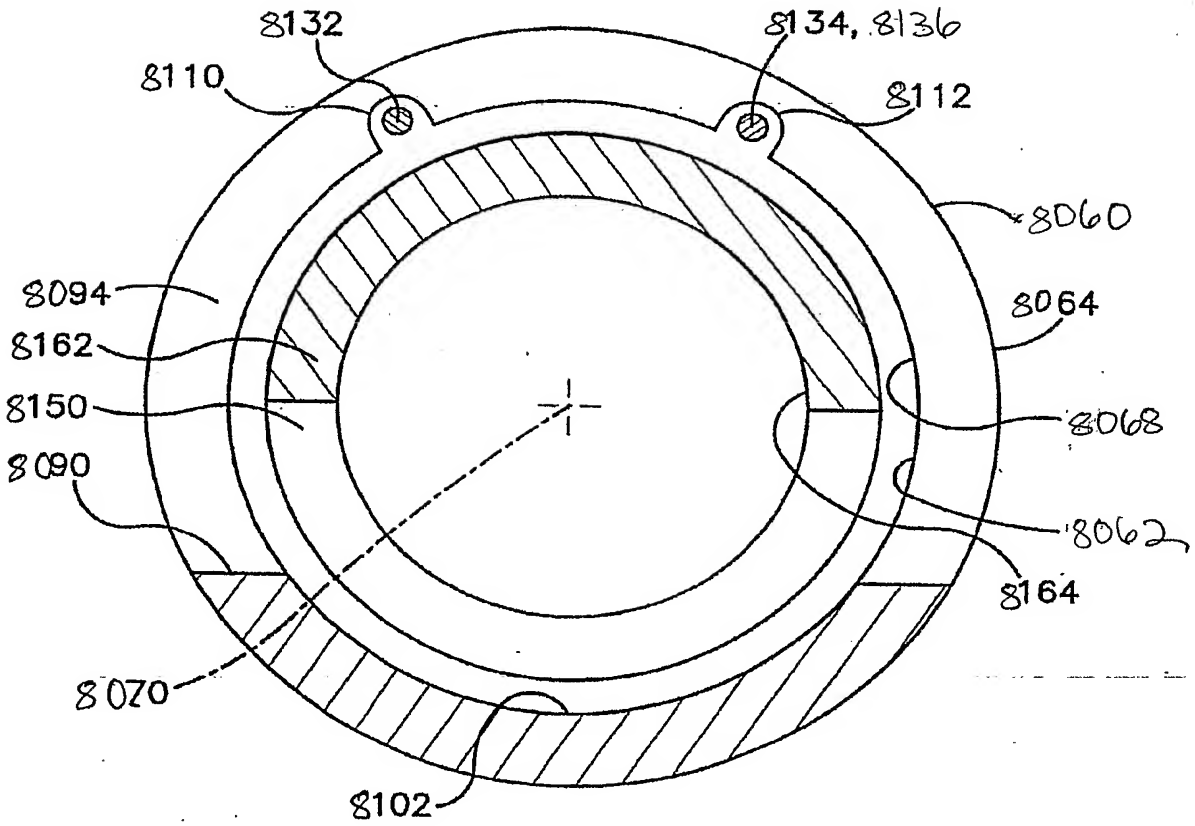


Fig. 119

Fig. 120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8134, 8136
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8102

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10/842,651	10 May 2004 (10.05.2004)	US

(71) Applicant *(for all designated States except US)*: **ENDIUS, INC.** [US/US]; 23 West Bacon Street, Plainville, Massachusetts 92762 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **DIPOTO, Gene** [US/US]; 23 Crockett Road, Upton, Massachusetts 01568 (US). **SHLUZAS, Alan** [US/US]; 84 Acorn Street, Millis, Massachusetts 02054 (US). **ROSSIN, Victor** [US/US]; 2 Kelly Road, Cambridge, Massachusetts 02139 (US). **ANDERSON, Stephen** [US/US]; 52 Sweetgrass Lane, Holliston, Massachusetts 01746 (US). **BAKER, Daniel** [US/US]; 13203 39th Ave. NE, #101, Seattle, Washington 98125-4615 (US).

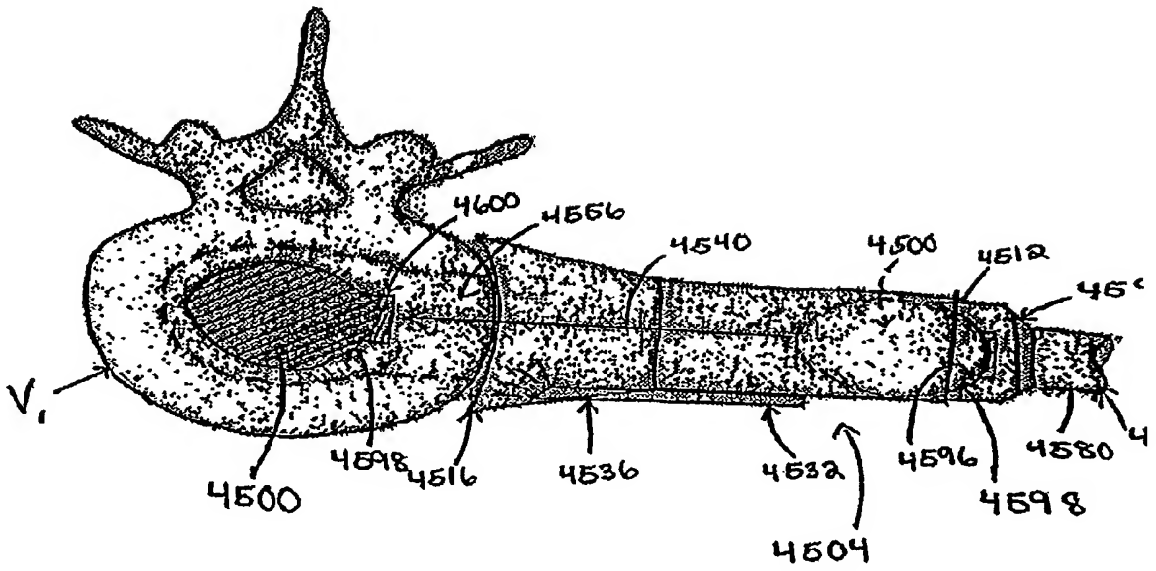
(74) Agent: **DELANEY, Karoline, A.**; 2040 Main Street, Fourteenth Floor, Irvine, California 92614 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH,

[Continued on next page]

(54) Title: METHODS, SYSTEMS AND APPARATUSES FOR PERFORMING MINIMALLY INVASIVE SPINAL PROCEDURES



(57) Abstract: In one embodiment, a surgical access device (5304a) comprising a passage and a distal portion (5324) may be used to perform a surgical procedure. The access device (5304a) may be actuatable between a first configuration wherein the passage has a first cross-sectional area at the distal portion (5324) suitable for insertion into the patient and a second configuration wherein the passage has an enlarged cross-sectional area at said distal portion (5324). The access device (5304a) may further be capable of providing access to a surgical location A. The passage is preferably capable of having an instrument (5376) or implant (5378) inserted therethrough to the surgical location A.

WO 2005/032358 A3

GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declaration under Rule 4.17:

— *of inventorship (Rule 4.17(iv)) for US only*

Published:

— *with international search report*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

(88) Date of publication of the international search report:
21 July 2005

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/S2004/033088

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B1/313 A61B17/34 A61B17/32 A61B17/70 A61F2/44
A61F2/46

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2003/073998 A1 (PAGLIUCA JAMES J ET AL) 17 April 2003 (2003-04-17) cited in the application	1-9, 11-13, 15,17, 19-28, 30-32, 34,41, 44,105, 106,110
Y	figures 33-45	10,29

X	US 2003/153927 A1 (DIPOTO GENE P ET AL) 14 August 2003 (2003-08-14) cited in the application	1-4,7,9, 10,12
Y	figures 1-6	10,29

	-/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
3 February 2005	10. 05. 2005

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Schießl, W

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INTERNATIONAL SEARCH REPORT

International Application No
PC[redacted]US2004/033088

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 6 053 907 A (ZIRPS ET AL) 25 April 2000 (2000-04-25) cited in the application column 1, line 54 - column 2, line 65 figures 1,2	10,29
Y	US 5 690 606 A (SLOTMAN ET AL) 25 November 1997 (1997-11-25) column 4, paragraph 3 figures 4,5	10,29

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2004/033088

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 72-104,111-148,150-167
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgeryRule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [X] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-13,15,17,19-32,34, 41,44,105,106,110

   An instrument having a working end articulatable from its proximal portion to increase the range of the working end

   ---

2. claims: 14,33

   An access device comprising a proximal portion that is expandable to provide an optimal opening for instruments of different cross-sections

   ---

3. claim: 16

   A registration paddle for locating the interbody space and for insertion through the passage at least partially into said space, serving as a place marker to register the location and orientation of the disc to be replaced

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4. claim: 18

   A guide attachable to the spine comprising a dovetail to engage instruments so that subsequent disc preparation and implant insertion procedures can be performed with greater ease and less reliance on endoscopic apparati

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5. claims: 35-40

   A replacement disc nucleus comprising an injectable material or an expandable element in order to provide the functions of the natural nucleus while preserving a degree of normal motion after recovery

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6. claims: 42,43,107-109

   An access device configered to be inserted into an annulus fibrosus to keep movement with respect to the disc to a minimum

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7. claims: 45-59

   A system including a motion preserving, stabilization device for attachment between at least two adjacent vertebrae to provide some stabilization while preserving motion

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8. claims: 60-71

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

A system including a fastener for transfacet fixation to minimize the stabilizer volume outside of the vertebrae

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9. claim: 149

A system including a bone probe to form a hole in a vertebra and a tap to thread said hole to prepare the vertebrae for a threaded fastener

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